Chapter 3 – Medicare Marketing Guidelines

For Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plans, and Section 1876 Cost Plans

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10 – Introduction

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These *Medicare* Marketing Guidelines reflect the Centers for Medicare & Medicaid Services' (CMS) current interpretation of the marketing requirements and related provisions of the Medicare Advantage (MA) and Medicare Prescription Drug Plan (PDP) rules (Chapter 42 of the Code of Federal Regulations, Parts 422 and 423). These *Medicare Marketing* Guidelines are for use by Medicare Advantage organizations offering MA plans and MA prescription drug (MA-PD) plans, *Section 1876 cost contracts*, and Prescription Drug plan (PDP) *sponsors.* These *Medicare M*arketing *G*uidelines are not applicable to Program of All-Inclusive Care for the Elderly (PACE) plans since PACE plans are governed by separate guidance which is not discussed in this document *or to Section 1833 cost plans*.

The scope of the term marketing, as used in the Medicare statute at Section 1851 (h) and 1860D-12 (b)(3)(D)(12) of the Act and CMS regulations extends beyond the public's general concept of advertising materials. Pursuant to 42 CFR 422.2260 and 423.2260 marketing materials include any informational materials targeted to Medicare beneficiaries.

In addition, CMS' definition of marketing extends beyond materials to include activities, conducted by the plan sponsor or an individual or organization on behalf of the plan sponsor, that steer or attempt to steer, a potential enrollee toward a plan, or limited number of plans, for which the individual or entity performing marketing activities expects compensation directly or indirectly for such marketing activities. As such, CMS' authority for marketing oversight encompasses various materials and activities.

It is important to note that the marketing guidance set forth in this document is subject to change *as policy, communication technology and industry marketing practices continue to evolve. It is the plan sponsor's responsibility to have a system in place that ensures all materials used in the marketplace meet current regulations and guidelines*. Moreover, the examples of marketing materials and promotional activities given in these *Medicare Marketing* Guidelines are not all-inclusive. Plan sponsors should apply the principles outlined in these *Medicare Marketing* Guidelines to all relevant decisions, situations, and materials. Any new rule-making or interpretative guidance (e.g., annual call letter or Health Plan Management System (HPMS) guidance memoranda) may update the marketing guidance provided here, and plan sponsors should use sound judgment and consult with CMS Account Managers in situations where new guidance updates the guidance provided in this document. Specific questions regarding a marketing material or any marketing practice should be directed to the plan's Account Manager or designated Marketing Reviewer.

20 - Definitions

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42 CFR 422.2, 422.4, 423.4, 422.2260, 423.2260, 422.2264, 423.2264, 422.2268, 423.2268, 422.2272, 423.2272

The following definitions *apply* for purposes of these *Medicare Marketing* Guidelines only.

Ad-hoc Enrollee Communications Materials

Enrollee communications materials are informational materials that are targeted to current enrollees, are customized or limited to a subset of enrollees, or apply to a specific situation, and which do not include information about the plan's benefit structure, but apply to specific situations or cover member-specific claims processing or other operational issues. These materials are not considered marketing materials. Examples of these materials included the following:

- *Letters about a shortage of formulary drugs due to a manufacturer recall letter;*
- *Letters to communicate that a beneficiary is receiving a refund or is being billed for underpayments; and*
- *Letters describing member-specific claims processing issues.*

Advertising

Advertising materials are primarily intended to attract or appeal to a potential plan sponsor enrollee. Advertising materials contain less detail than other marketing materials, and may provide benefit information at a level to entice a potential enrollee to request additional information.

Examples of advertising materials include:

- Television ads
- Radio ads
- Outdoor advertising (ODA) such as billboards or signs attached to transportation vehicles
- Banner and banner-like ads
- Print ads (newspaper, magazine, flyers, brochures, posters, church bulletins)
- Post stands and free standing inserts (newspapers, magazines)
- Event signage
- Internet advertising
- Pharmacists' promotional buttons
- Window stickers

- Counter tents

- Direct mail *includes items such as postcards*, self mailers, home delivery coupons, and reply cards ***as*** *long as they do not include enrollment forms*.

Assisting in Enrollment

Assisting in enrollment consists of assisting a potential enrollee with the completion of an application and/or objectively discussing characteristics of different plans to assist a potential enrollee with appraising the relative merits of all available individual plans, based solely on the potential enrollee's needs. As used in these *Medicare Marketing* Guidelines, the phrase "assisting in enrollment" does not apply to assistance being provided by an individual or entity receiving direct or indirect compensation from the company with which the beneficiary is considering enrolling.

Banner and Banner-Like Advertisements

Banner advertisements are typically used in television ads, and flash information quickly across a screen with the sole purpose of enticing a prospective enrollee to contact the plan sponsor to enroll or for more information. A "banner-like" advertisement is usually in some media other than television (for example, outdoor advertising and internet banner ads) and is intended to be very brief and to entice someone to call the plan sponsor or to alert someone that information is forthcoming.

Co-Branding

Co-branding is defined as a relationship between two or more separate legal entities, one of which is an organization that sponsors a Medicare plan. The plan sponsor displays the name(s) or brand(s) of the co-branding entity or entities on its marketing materials to signify a business arrangement. Co-branding arrangements allow a plan sponsor and its co-branding partner(s) to promote enrollment in the plan. Co-branding relationships are entered into independently from the contract that the plan sponsor has with CMS.

Corporate Website

An organization's web page may include information on the organization's mission, history, contact information, products and services.

NOTE: All plans are required to have a website with the web address provided in the HPMS contract management module. A web address is an address that is typed into the web browser, also known as a URL (Universal Resource Locator). A web link is a shortcut within a website or web page that connects the user to another location on the Internet. A web page is a single element of a website, usually an HTML-based document exclusively dedicated to a specific product (e.g., MA-PD plan or PDP).

Direct mail

Is information sent to a beneficiary to attract attention or interest to a potential enrollee and allow him/her to request additional information.

Education

Informing a beneficiary about Original Medicare, MA plan, MA-PD plans or PDPs in an unbiased way that does not steer, or attempt to steer, that enrollee toward a specific plan or limited number of plans.

Educational Event

An event hosted by the plan sponsor or an outside entity is considered an education event if the event is advertised to beneficiaries as "educational." Educational events may not include any sales activities such as the distribution of marketing materials or the distribution or collection of plan applications.

(The intent of this guidance is not to preclude plans from educating beneficiaries about their products; rather it is to ensure that events that are advertised as "educational" comply with CMS' requirements. More specifically, plans may provide education at a sales or marketing event, but may not market or sell at an educational event.)

Explanatory Marketing Materials

Explanatory marketing materials are a subset of marketing materials primarily intended to explain the benefits, operational procedures, cost sharing, and/or other features of a plan sponsor to current members or to those considering enrollment. Explanatory marketing materials are further subdivided into enrollment materials, pre-enrollment marketing materials and post-enrollment marketing materials, all of which are defined in § 20.

Enrollment Materials

Enrollment materials are materials used to enroll or disenroll from a plan, or materials used to convey information specific to enrollment and disenrollment issues such as enrollment and disenrollment forms.

NOTE: Refer to Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Prescription Drug Benefit Manual for model enrollment forms and notices.

Field Marketing Organization (FMO)

A third party entity such as a field marketing organization or similar type entity that has been retained to sell or promote a plan's Medicare products on the plan's behalf either directly or through sales agents or a combination of both.

Health Plan Management System (HPMS)

A web-enabled information system that serves a critical role in supporting the implementation and ongoing operations of the MA plans, MA-PD plans, section 1876 cost plans and PDPs. HPMS and its software modules are used to collect and receive data.

Joint Enterprise

A joint enterprise is a group of organizations that are State licensed as risk-bearing entities that jointly enter into a single contract with CMS to offer a Regional Preferred Provider Organization (RPPO) plan or PDP in a multi-State region. The participating organizations contract with each other to create a single "joint enterprise" and are considered an "entity" for purposes of offering a RPPO or PDP.

Local Plans

A local plan is offered by a legal entity that is not a regional or national plan. Plan sponsors may choose the counties in which local plans operate. Local plans may also vary benefits and premiums at the county level. The uniform benefit requirement applies to local plans at the service area or segment level.

NOTE: PDPs **cannot** offer a local plan.

Marketing

Steering, or attempting to steer, a potential enrollee towards a plan, or limited number of plans. "Assisting in enrollment" and "education" do not constitute marketing.

CMS' authority for marketing oversight extends to include a range of different marketing materials and activities. While not an exhaustive list, the following would fall under CMS' purview per the definition of marketing:

- General audience materials such as general circulation brochures, direct mail, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.
- Marketing representative materials such as scripts or outlines for telemarketing or other presentations.
- Presentation materials such as slides and charts.
- Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).
- Membership communications and communication materials including membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.
- *Communications* to members about contractual changes, and changes in providers, premiums, benefits, plan procedures, etc.

- Membership *activities (for example*, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, *or non-claim specific* notification information.)

- The activities of a plan sponsor's employees, independent agents or brokers, subcontracted FMOs or other similar type organizations that are contributing to the steering of a potential enrollee toward a specific plan or limited number of plans, and may receive compensation directly or indirectly from a plan sponsor for marketing activities.

Marketing Materials

The definition of marketing materials, as used in CMS regulations and these *Medicare Marketing* Guidelines extends beyond the public's general concept of advertising materials. Marketing materials include any informational materials targeted to Medicare beneficiaries which:

- Promote the plan sponsor, or any MA *plan, MA-PD plan, Section 1876 cost plan*, or PDP offered by the plan sponsor.

- Inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA *plan, MA-PD plan, Section 1876 cost plan,* or PDP offered by the plan sponsor.

- Explain the benefits of enrollment in an MA plan, *MA-PD plan, Section 1876 cost plan*, or PDP or rules that apply to enrollees.

- *Explain how Medicare services are covered under an MA plan, MA-PD plan, Section 1876 cost plan or PD Plan, including conditions that apply to such coverage.*

Marketing/Sales Event

Marketing/sales events are events that a plan sponsor hosts or participants in aimed at promoting specific benefits/premiums and/or services offered by the plan. Plan sponsors may conduct a formal event where a presentation is provided to Medicare beneficiaries or an informal event where plan sponsors are only distributing health plan brochures and pre-enrollment materials. Plan sponsors may also accept enrollment forms and perform enrollment at marketing/sales events.

Medicare Advantage (MA) Organization

An organization that is a public or private entity organized and licensed by a State as a risk-bearing entity that is certified by CMS as meeting the requirements to offer an MA plan.

Medicare Advantage (MA) Plan

A plan that offers coverage of Medicare Part A and Part B benefits, and which may also offer other benefits, including Part D coverage, at a uniform premium and uniform level of cost-sharing to individuals living in the service area who are entitled to benefits under Medicare Part A and enrolled in Part B.

Medicare Advantage Prescription Drug (MA-PD) Plan

An MA plan that provides qualified prescription drug coverage.

Medigap

A Medicare supplemental (Medigap) policy is a health insurance policy sold by private insurance companies specifically to fill "gaps" in Original Medicare coverage. A Medigap policy typically pays some or all of the deductible and coinsurance amounts applicable to Medicare-covered services and sometimes covers items and services that are not covered by Medicare, such as care outside of the country.

Model Document

For certain beneficiary informational documents, CMS has provided model language, which when used without modification, except within bracketed areas, entitles the plan sponsor to receive a shorter review period or to submit under File & Use as outlined in § 90.6.1. *The use of CMS model documents is optional unless otherwise directed by CMS or if the material falls into the category of standardized model materials (refer to § 90.7.2).* Plan sponsors that choose to create their own language must be sure to include all information that is in the model document.

Multi Contract Entities (MCE)

A designation available for plan sponsors that have multiple MA/PDP contracts with CMS. Being designated as an MCE allows plans to submit template materials to CMS that are representative of all or a selection of the plan sponsors' contracts. The plan sponsors' Account Manager has the ability to approve requests for MCE designation once a plan sponsor requests the designation. Please note that, in most instances, MCE has replaced the designation of Multi-Regional Teams (MRTs)/Multi-Contract Groups (MCGs) and if a plan has already attained an MRT/MCG status no action is needed to convert it to MCE status.

National Plans:

- **National (PDPs):** The term "national plan" means a PDP sponsor that, at a minimum, offer plans in each of the 34 PDP regions that include the 50 States and the District of Columbia. PDP sponsors that offer plans in more than the minimum 34 PDP regions (e.g., those that include the 50 States, the District of Columbia, and one or more territories) are also considered national plans. PDPs sponsored by a joint enterprise, can also use the term "national" if the joint enterprise offers plans, at a minimum, in all 34 PDP regions that include the 50 States and the District of Columbia. (Refer to Federal Register Vol. 70 FR 13398.)

- **National Medicare Advantage and Medicare Advantage Prescription Drug (MAs/MA-PDs) Plans:** The term "national plan" means a Medicare Advantage Organization (MAO) that offers MA/MA-PD plans in each of the 50 States and the District of Columbia. An MA or MA-PD is considered to be a national plan regardless of whether or not the MAO offers a plan in one or more of the territories.

Nominal Value

Any promotional activities or items offered by plan sponsors, including those that will be used to encourage retention of members, must be of nominal value. Nominal value is currently defined as an item worth $15 or less, based on the retail purchase price of the item. Note that CMS sets the maximum, not the minimum for nominal gifts.

Outdoor Advertising (ODA)

Marketing material intended to capture the attention of an audience passing the outdoor display (e.g., billboards, signs attached to transportation vehicles) and to influence them to request more detailed information on the product being advertised.

Part C Program

A term used to describe the program *encompassed by all plan sponsors offering MA or MA-PD coverage.*

Part D Program

A term used to describe the program encompassed by all plan sponsors offering Part D prescription drug coverage.

Part D Sponsor or Part D Plan Sponsor

A Part D sponsor is an MAO that offers an MA-PD plan, a PDP sponsor offering a PDP, or a section 1876 cost plan offering qualified prescription drug coverage.

Plan Benefit Package (PBP)

The package of benefits to be offered in a specific geographic area by an MA plan, MA-PD plan, PDP, section 1876 cost plan or employer group waiver plan, filed annually with CMS for approval.

NOTE: For purposes of this guidance the term "plan" will be utilized to describe all plan types unless otherwise noted.

Plan Sponsor

The term "plan sponsor" is utilized in these *Medicare Marketing* Guidelines to refer to the entity that has a contract with the Federal Government to offer one or all of the following Medicare Products: MA plans, MA-PD plans, PDPs, and section 1876 cost plans.

NOTE: For purposes of this guidance the term "plan sponsor(s)" will be utilized to describe all organizational/plan types unless otherwise noted.

Post-Enrollment Marketing Materials

A subset of explanatory marketing materials used by a plan sponsor to convey benefits or operational information to current enrollees. Post-enrollment marketing materials include but are not limited to:

- All notification forms, letters and sections of newsletters that are used to communicate with the individual on various membership operational policies, rules, and procedures
- Annual Notice of Change (ANOC)
- Enrollment Letters
- Evidence of Coverage (EOC)
- Pharmacy directory
- Provider directory
- Formulary
- Member ID card
- Grievance, coverage/organization determination, and appeals letters
- Exceptions process letters
- Member handbook

Pre-Enrollment Marketing Materials

A subset of explanatory marketing materials, pre-enrollment materials (e.g., sales scripts, direct mail that includes an enrollment form, sales presentations) are generally used by prospective enrollees to decide whether or not to enroll in a plan. Pre-enrollment materials may contain plan rules and/or benefits information. Pre-enrollment marketing materials include but are not limited to:

- Sales scripts/sales presentations
- Direct mail that includes an enrollment form
- Sales presentation materials
- Summary of Benefits (SB)

Promotional Activities

Activities performed by a plan, or by an individual or organization on a plan's behalf, to inform current and potential enrollees of the products available. Promotional Activities typically provide a higher level of detail than general advertising.

Regional Plans

- **PDP Regional Plan:** A regional PDP sponsor offers PDP plans that serve one or more entire PDP region(s), but not all 34 PDP regions that include the 50 States and the District of Columbia.

- ***MA/MA-PD Regional Plans*:** An MA or MA-PD regional plan is a coordinated care plan structured as a Preferred Provider Organization (PPO) that serves one or more entire MA region(s) but not all 26 MA regions that include the 50 States and the District of Columbia.

Sales Person

The term "sales person" is used in these Medicare Marketing Guidelines to define an individual who markets and/or sells products for a single plan sponsor or numerous plan sponsors. It includes employees, brokers, agents, and all other individuals, entities, and downstream contractors that may be utilized to market and/or sell on behalf of a plan sponsor.

Section 1876 cost plan

A plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under Section 1876 of the Social Security Act.

Standardized Language

Language developed by CMS or other Federal agencies which is mandatory for use by the plan sponsor and **cannot** be modified.

State Pharmaceutical Assistance Program (SPAP)

An SPAP is a State program which provides financial assistance for supplemental prescription drug coverage for Part D eligible individuals.

Template Materials

Template materials are any marketing materials that include placeholders to be populated by variable elements.

Value Added Items and Services (VAIS)

VAIS are non-benefit items and services provided to a plan sponsor's enrollees. An item or service is classified as a VAIS if the cost, if any, incurred to the plan sponsor in providing the item or service, is solely administrative. A cost is not automatically classified as administrative simply because it is either minimal or non-medical. The cost, if any, must be intrinsically administrative; the cost must cover such items as clerical or equipment and supplies related to communication (such as phone and postage), or database administration (such as verifying enrollment or tracking usage).

Note that this definition does not require that VAIS be health-related. A VAIS is not a benefit since no direct medical or pharmaceutical cost is incurred to the plan sponsor in providing the VAIS.

30 - Plan Sponsor Responsibilities

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30.1 - Limitations on Distribution of Marketing Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262(a), 423.2262(a), 422.2260, 423.2260

A plan sponsor is prohibited from advertising outside of its defined service area unless such advertising is unavoidable. For situations in which this cannot be avoided (e.g., advertising in print or broadcast media with a national audience or with an audience that includes some individuals outside of the service area, such as a Metro Statistical Area that covers two regions), *plan sponsors are required to clearly disclose their service area.*

NOTE: *Dual-Eligible (DE) SNPs are responsible for making sure that the service area in which they market is consistent with the service area covered by the State and is included in applicable State contracts.*

30.2 - Co-branding Requirements

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

CMS permits plan sponsors to enter into co-branding arrangements as provided in this section. The following guidelines should be followed in the case of a co-branding arrangement:

- *To ensure that CMS is made aware of any such relationships, the plan sponsor must inform its CMS Account Manager of any co-branding relationships at the time that the plan sponsor begins to input the co-branding relationships in the Health Plan*

Management System (HPMS). The HPMS submission module will allow plan sponsors to indicate whether they are co-branding with specific entities for specific services. (Refer to the HPMS user manual for instructions.)

- Any changes in or newly formed co-branding relationships during the year should be communicated by the plan sponsor to its CMS Account Manager. The plan sponsor should also input this information in HPMS prior to marketing its new relationship. The plan sponsor should also remove any references to and former co-branding partner(s) from its marketing materials as applicable.

- *The plan sponsor is responsible for ensuring that its co-branding partner(s) also adhere(s) to all applicable CMS policies and procedures.*

- The plan sponsor should attest that its co-branding partners were provided with these *Medicare* Marketing Guidelines and that the co-branding partners agree to follow these guidelines with respect to all marketing materials related to the plan sponsor.

In addition, plan sponsors are permitted to display the names and/or logos of non-provider entities not having substantially similar names and/or logos of a network provider or providers on all marketing materials (including the member identification card).

Co-branding information added to previously approved template materials is not subject to re-review, as long as the changes are limited to populating existing variable fields (e.g., organization name, logos, or contact information).

30.2.1 - *Co-branding with Network Providers*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

In addition to the above requirements, plan sponsors are prohibited from displaying the names and/or logos of co-branded network providers on the plan sponsor's member identification card, unless the provider names, and/or logos are related to a member's selection of specific provider/provider organization (for example, physicians, and hospitals).

Plan sponsors that choose to co-brand with network providers must include on marketing materials other than ID cards the following language:

"Other <Pharmacies/Physicians/Providers> are Available in Our Network."

All co-branding names and/or logos of providers and/or pharmacies should be on all other marketing materials. Neither the plan sponsor nor its co-branding partners, whether through marketing materials or other communications, may imply that the co-branding partner is endorsed by CMS, or that its products or services are Medicare-approved. Co-branded marketing materials must be compliant with the *Medicare* Marketing Guidelines and must be submitted to

CMS by the plan sponsor. Plan sponsors may elect to submit co-branded materials as template materials.

30.2.2 - Co-Branding with State Pharmaceutical Assistance Programs (SPAP)

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

A plan sponsor's logo may be used in connection with the coverage of benefits provided under an SPAP and may contain an emblem or symbol indicating such a connection. The decision to "co-brand" with SPAPs resides with the plan sponsor. There is nothing in the statute that requires the plan sponsor to add the SPAP emblem to its card. Therefore, if an SPAP approaches a plan sponsor to request that its emblem or symbol be placed on the cards (as well as other marketing materials), the plan sponsor may decide not to co-brand. States have asked if they can choose which plan sponsors to co-brand with, or if they must offer to co-brand with all plan sponsors.

CMS believes that SPAPs should offer co-branding of materials, including the identification card, to all plan sponsors covering the service area of the SPAP. It is entirely the plan's sponsor's decision whether or not to co-brand with the SPAP. If a plan sponsor approaches the State to co-brand, the SPAP may do so. It should be noted that both the SPAP and the Part D plan sponsor should notify the plan's Account Manager in advance of the co-branding arrangement and must agree to adhere to all applicable Medicare Marketing Guidelines.

States have also asked whether it would be discriminatory if the SPAP, during its education and outreach campaign, informed the beneficiary which plan sponsors have agreed to co-brand. We do not believe that this would discriminate against other plan sponsors, as long as all plan sponsors have been offered the option to co-brand with the State and the standards for co-branding offered by the State do not vary materially from one plan to another. In other words, as long as the SPAP gives all Part D plan sponsors equal opportunity to co-brand with them and is providing the same benefits for all beneficiaries regardless of the co-branded plan sponsors, the SPAP is not discriminating.

Co-branding relationships that involve remuneration between parties in a position to influence the referral of Medicare-payable business should carefully scrutinize the relationship for compliance with the fraud and abuse laws, including the Federal anti-kickback statute.

30.3 - Provider Name in Plan's Name or Downstream Entity's Name

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Plan sponsors whose legal or marketing names include the logos and/or names of network providers, or whose downstream entities' legal or marketing names include the logos and/or

names of network providers, are required to include the following language below on *all of* their marketing materials. *Plan sponsors have discretion regarding placement of the disclaimer provided it is placed in a visible location.*

"Other <Pharmacies/Physicians/Providers> are Available in Our Network."

The plan sponsor, its downstream entities, and its network providers, whether through marketing materials or other communications, may not imply that the network provider is endorsed by CMS, or that their products or services are Medicare-approved.

30.4 - Use of Data from Medigap Issuers

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

If a Medigap issuer chooses to sponsor an MA plan, MA-PD plan, section 1876 cost plan, or PDP, it is permitted to use its current Medigap plan enrollment information to market the MA, MA-PD, cost, or Part D plan to those enrollees, to the extent permitted by the HIPAA Privacy Rule and other applicable Federal or State privacy laws. However in doing so, the Medigap issuer/plan sponsor may not conduct outbound calls to market its MA, MA-PD, cost or Part D plans. The Medigap issuer/plan sponsor may conduct other marketing activities related to its MA, MA-PD, cost or PDP plans to all current Medigap enrollees, not just a subset. Additionally, the Medigap issuer/plan sponsor must adhere to all HIPAA Privacy Rules and other applicable Federal or State privacy laws. Refer to § 30.6, 70.4, and 70.9.1 for additional information.

If during the course of an outbound call regarding Medigap products, the beneficiary initiates interest in an MA, MA-PD, cost plan, or PDP product offered by the Medigap issuer, then that MA, MA-PD, cost plan, or PDP product may be discussed, as long as the call is recorded. (Refer to §70.4 on unsolicited contact.)

30.5 - Plan Sponsor Responsibility for Subcontractor Activities and Submission of Materials for CMS Review

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

422.504 (h)(1), 422.504(h)(2)(i), 423.505(h)(1), 423.505(h)(2)(i), 422.2262, 423.2262

Plan sponsors that contract with CMS are responsible for all activities undertaken by their subcontractors on their behalf, including, but not limited to, all materials used that meet CMS' definition of a marketing material, all sales activities, and any and all scripts used to facilitate a sale.

CMS must review all applicable marketing materials prepared by a plan sponsor's sub-contractor(s) excluding marketing materials for employer/union enrollees. Marketing materials

may not be submitted directly by the third party to CMS; rather materials must be submitted directly by the plan sponsor that contracts with CMS (e.g., the MAO or PDP sponsor offering the plan being marketed). It is the responsibility of the plan sponsor to ensure that all applicable materials created by a third party meet the requirements as outlined in these *Medicare Marketing* Guidelines. When a sub-contractor wants to use material previously approved by CMS, it must inform the plan sponsor. To that end, it is the responsibility of the plan sponsor to have a system in place to account for and control the materials that are being utilized by all third party contractors.

Employer group health plans should refer to §130 of this chapter, § 20.3 of Chapter 9 of the Medicare Managed Care Manual, and § 20.3 of Chapter 12 of the Prescription Drug Benefit Manual for more guidance.

30.5.1 - *Multiple Organization Marketing Pieces Created by Agents*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

422.2262, 423.2262

Third party marketing materials, including materials created by agents/brokers, must be submitted to the plan sponsor prior to use for review and approval and follow the guidance in § 30.5 and 120.4. Materials that are generic in nature and do not discuss content specific to plan benefits or cost-sharing or include plan names will not require review and approval. Generic materials may reference the different product types (e.g., MA plan, MA-PD plan, *section 1876 cost* plan, PDPs) offered by the agent.

NOTE: This guidance is not applicable to employer group health plan materials; refer to §130 of this chapter as well as § 20.3.2.1.1 of Chapter 9 of the Medicare Managed Care Manual and § 20.3.2.1.1 of Chapter 12 of the Prescription Drug Benefit Manual for more detail.

30.6 - Anti-Discrimination

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.110, 422.2268(c), 423.2268(c)

Plan sponsors may not discriminate based on race, ethnicity, religion, gender, sexual orientation, disability, health status, or geographic location within the service area. All items and services of a plan sponsor are available to all eligible beneficiaries in the service area with the following exceptions:

- Certain products and services may be made available to enrollees with certain diagnoses (e.g., medication therapy management program for individuals with chronic illnesses or medically necessary coverage provisions).

- Enrollment in the low income subsidy (LIS), as there may be additional eligibility standards.

NOTE: *As provided in §20.2 of Chapter 2 of the Medicare Managed Care Manual, an individual is generally not eligible to elect an MA plan if he/she has been medically determined to have ESRD.*

Plan sponsors may not engage in discriminatory practices such as targeting marketing to beneficiaries from higher income areas. Additionally, plan sponsors may not state or otherwise imply that plans are available only to seniors rather than to all Medicare beneficiaries. Only SNP sponsors may limit enrollment to dual-eligibles, institutionalized individuals, or individuals with severe or disabling chronic conditions and/or may target items and services to corresponding categories of beneficiaries.

30.7 - Requirements for Plan Sponsors with Non-English Speaking Populations or Populations with Special Needs

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264(e), 423.2264(e)

Plan sponsors must make the marketing materials noted in § 30.9, 30.10 and 30.11 available in any language that is the primary language of more than ten percent of a plan sponsor's PBP service area. Additionally, plan sponsors must place translated versions of these materials on the plan's website. For example, contract ID HXXXX includes plan 001. The plan sponsor's PBP service area would be the counties that are covered by plan 001. CMS expects plans operating in areas where the ten percent language requirement threshold is met will provide non-English materials upon beneficiary request. Regardless of the percentage of non-English speakers in a service area, all plan sponsors' call centers must be able to accommodate non-English speaking/reading beneficiaries. Plan sponsors must have appropriate interpreter services available to call center personnel to answer questions from non-English speaking beneficiaries.

In addition, basic enrollee information must be made available to individuals with disabilities (for example, visually impaired beneficiaries). Plan sponsors must make sure information about their benefits is accessible and appropriate for Medicare beneficiaries who have disabilities.

CMS expects that translated versions of materials will be proactively uploaded in HPMS and that requests for translated materials be provided to beneficiaries in a reasonable timeframe. Plan sponsors will be subject to verification monitoring review and penalties for violation of these requirements. In addition to verifying the accuracy of non-English marketing materials through monitoring review, CMS will also periodically conduct marketing reviews of non-English materials and non-traditionally formatted information (e.g., Braille) on an "as needed" basis. If materials are found inaccurate or do not convey the same information as the English version, plan sponsors may be subject to compliance or enforcement action and may not distribute materials until revised materials have been approved. (Refer to Appendix 2,

"Attestation Form for Translated Non-English or Alternate Materials" and § 90.11 for information on how to submit non-English or alternate materials via HPMS.)

30.8 - Compliance with Section 508 of the Rehabilitation Act

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. § 794 (d)), as amended by the Workforce Investment Act of 1998 (P.L. 105-220), August 7, 1998

All plan sponsors are required to have an internet website that is compliant with web-based technology and information standards for people with disabilities as specified in Section 508 of the Rehabilitation Act. (Refer to § 100 for details.)

30.9 - Required Materials in Enrollment Kit

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111, 423.128

When a beneficiary is provided marketing materials for the purpose of enrollment/potential enrollment, the information listed below must be included. This, in total, represents an "Enrollment Kit". When a plan sponsor enrolls a beneficiary online, it must make these materials available electronically (for example via website links) to the potential member prior to the completion and submission of the enrollment request. Beneficiaries must have access to enrollment materials either electronically or via hard copy to ensure this information is received prior to completion of the enrollment request. Plan sponsors must ensure that all appropriate disclaimers are on the materials specified below (refer to § 50 for disclaimers).

Note that if the information below is contained elsewhere in one of the documents of the enrollment kit, plans are not required to create a separate document containing that specific information. For example, if the written notice on LIS is already contained within the enrollment kit, then plans do not have to create a separate document with the LIS disclaimer.

- A cover letter including the plan's toll-free customer service telephone number, a TTY telephone number, customer service hours of operation, and a physical or post office address. The letter must indicate that beneficiaries may contact 1-800-MEDICARE (1-800-633-4227), or visit http://www.medicare.gov for more information about Medicare benefits and services including general information regarding health or Part D benefits. The cover letter may include website URL for the plan sponsor. Plan sponsors should use the URL that will take beneficiaries directly to the Medicare plan information page.

- Enrollment instructions and forms.

- *Written notice that plan benefits and cost-sharing may change from year to year. (Refer to § 50.1.3 for disclaimers regarding benefits.)*

- Written explanation of plan's grievance, coverage/organization determination (including exceptions) and appeals processes, including differences between the processes and when it is appropriate to use each.

- *Written notice that a plan may not be available to the beneficiary the following contract year because by law, plan sponsors can choose to not renew their contract with CMS or reduce their service area and CMS may also refuse to renew the contract, thus, resulting in a termination or non-renewal.*

- **Written notice on LIS including the following text**: "People with limited incomes may qualify for Extra Help to pay for their prescription drug costs. If eligible, Medicare could pay for *up to one-hundred (100*) percent of drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify will not be subject to the coverage gap or a late enrollment penalty. Many people are eligible for these savings and don't know it. For more information about this Extra Help, contact your local Social Security office or call 1-800-MEDICARE (1-800-633-4227), 24 hours per day, 7 days per week. TTY users should call 1-877-486-2048."

- *Plan ratings information on http://www.medicare.gov must be submitted as a standalone document. Refer to § 30.16 for more details about plan ratings information.*

- *Summary of Benefits (SB)*

Plan sponsors have the option of including the following materials in their enrollment kits but must make them available upon request. *However, if a beneficiary enrolls with the plan sponsor, the materials below must be distributed to him/her no later than ten (10) calendar days from receipt of CMS confirmation of enrollment or by the last day of the first month of enrollment, whichever occurs first.*

- Pharmacy directory (Part D sponsors only)

- Provider directory

- *Combined provider/pharmacy directory (refer to § 60.4.4 for additional requirements.)*

- Comprehensive or abridged formulary (Part D sponsors only)

30.10 - Required Materials for New and Renewing Members at Time of Enrollment and Annually Thereafter

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111, 423.128, 422.2264, 423.2264

Within the timeframes specified by CMS, plan sponsors must provide members with all necessary information outlined in Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual. In addition, the materials below must be distributed to a beneficiary no later than ten (10) calendar days from receipt of CMS confirmation of enrollment or by the last day of the first month of enrollment, whichever occurs first. Plans should refer to the notification on the weekly or monthly Transaction Reply Report (TRR) that contains the earliest notification to identify the start of the ten (10) calendar day timeframe.

- *Annual Notice Of Change /Evidence Of Coverage (ANOC/EOC) or EOC as applicable (except for DE SNPs; refer to § 60.7 for more information about these requirements);*
- Comprehensive formulary or abridged formulary including information on how the beneficiary can obtain a complete formulary (Part D sponsors only)
- Pharmacy directory (For all plan sponsors offering a Part D benefit)
- Provider directory (All plan types except PDPs)
- Membership identification card (required only at time of enrollment and as needed or required by plan sponsor post-enrollment)

30.11 - Required Ongoing Materials for New and Renewing Members

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.128(e)

Only those plan sponsors offering Part D must provide their enrollees an Explanation of Benefits (EOB) on at least a monthly basis for those months in which the enrollees use their Part D benefits. Refer to § 60.6 for more information about the EOB.

30.12 - Hold Time Messages

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268 (f) and 423.2268(f)

Hold time messages (recorded information played to caller while waiting on hold) that discuss health-education features and other general information (e.g., hours of operation, flu shot reminders) are allowed. Hold time messages that include information regarding disease management programs or health education or other generic statements such as "Thank you for holding" will not require CMS review and approval. However other health related features on hold time messages should be submitted for a forty-five (45) day review. Plan sponsors may not

include non-health related services (e.g., financial service information) on hold time message. Refer to § 80.1.4 for additional information on scripts.

30.13 - Use of the Medicare Name

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

Under Section 1140 of the Social Security Act, 42 U.S.C. 1320b–10, it is forbidden for any person to use words or symbols, including "Medicare," "Centers for Medicare and Medicaid Services," "Department of Health and Human Services," or "Health and Human Services" in a manner that would convey the false impression that the business or product is approved, endorsed, or authorized by Medicare or any other government agency. This rule extends to downstream contractors that may be directly or indirectly involved in marketing Medicare plans. Plan sponsors should ensure that their subcontractors are not using the Medicare name in a misleading manner.

30.14 - Referral Programs

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

The following general guidelines apply to referral programs under which a plan sponsor solicits leads from members for new enrollees. These include gifts that would be used to thank members for devoting time to encouraging enrollment. Gifts for referrals must be available to all members that provide a referral and **cannot** be conditioned on actual enrollment of the person being referred.

- *A plan sponsor can ask for referrals from active members, including names and addresses, but cannot request phone numbers. Plan sponsors may use member provided referral names and addresses to solicit potential new members by mail only***.**

- Any solicitation for leads, including letters sent from plan sponsors to members **cannot** announce that a gift will be offered for a referral.

- Plan sponsors may not use cash promotions as part of a referral program

- Plan sponsors may offer thank you gifts that are worth $15 or less, based on the retail purchase price of the item (e.g., thank you note, calendar, pen, key chain) when an enrollee provides a referral as a result of a plan's solicitation for referrals. These thank you gifts are limited to one gift per member, per calendar year.

30.15 - Privacy and Confidentiality

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.118, 422.752(a)(4), 423.136, 423.752(a)(4)

Plans and providers are responsible for following all Federal and State laws regarding confidentiality and disclosure of patient information to plan sponsors for marketing purposes. This obligation includes compliance with the provisions of the HIPAA Privacy Rule and its specific rules regarding uses and disclosures of beneficiary information. In addition, plan sponsors are subject to sanction for engaging in any practice that may reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services *(e.g., health screening or "cherry picking"). HIPAA and privacy documents (e.g., a HIPAA/privacy document for a beneficiary's signature in a provider's office) are not considered marketing documents and therefore do not need to be submitted in HPMS.. Refer to § 90.21 regarding materials not subject to review. Additional information on the HIPAA Privacy Rule and its disclosure requirements can be found at http://www.hhs.gov/ocr/privacy/.*

30.16 - Plan Ratings Information from ***www.medicare.gov.***

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264(a)(4), 423.2264(a)(3)

The Medicare program rates how well plan sponsors perform in different categories, for example, detecting and preventing illness, ratings from patients, patient safety and customer service and other measures. Plan sponsors must provide information about their plan or plans' ratings information to current and prospective enrollees by referring them to http://www.medicare.gov in all enrollment kits, including it in their enrollment kits, and making it available upon request. Information from http://www.medicare.gov and the HPMS generated plan ratings document described below may not be altered in any way.

Plan sponsors must download their 2010 plan performance rating template generated from the HPMS Part D Performance Metrics Module using the following navigation path: HPMS Homepage>Quality and Performance>Part D Performance Metrics and Reports> Plan Ratings Template. Plan sponsors will select their contract number from the list and click on the "Create PDF" link to generate their customized contract-specific template in PDF format, which may not be altered. Plan performance summary ratings for each upcoming contract year will not be available until the fall of each year. MA-PD plans must download separately plan performance ratings for each MA and Part D contract.

Plan performance summary ratings for the following contract year will not be available until early October of each year. Thus, plan sponsors must provide plan ratings templates (which is

generated from HPMS), and include them in their enrollment kits, using the prior year's template information until such time as the template for the following contract year is made available. Once the current year's plan performance rating template is available , plan sponsors may update the enrollment kit to ensure the most up-to-date plan performance ratings is provided to current and prospective enrollees. New plans that do not have any plan ratings information are not required to provide plan ratings information until the new contract year.

40 - General Marketing Requirements

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

40.1 - Marketing Material Identification Number

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262, 422.2264, 423.2264

Plan sponsors are required to place a unique marketing material identification number on all marketing materials. This information will allow CMS to track the plan sponsor's marketing material within the marketplace and address beneficiary inquiries and/or complaints should they arise. This number is also used to identify and track materials in HPMS.

CMS requires a specific format for this identifier to allow immediate recognition of the document and/or advertisement as a Medicare marketing material. When submitting the material in HPMS, the material ID is made up of three parts. This system allows each material to be identified by the specific plan sponsor while allowing the plan sponsor the freedom to develop its own filing system for its materials. The material ID must be entered into HPMS in the same manner that it appears on the marketing material submission.

The first part of the material identification number is the plan sponsors' contract number (H for MA or section 1876 cost plans, R for regional PPO plans (RPPOs), or S for PDPs) or Multi-Contract Entity (MCE) identifier (Y) followed by an underscore. The second part of the identifier is any series of alpha numeric characters chosen at the discretion of the plan sponsor. The third part includes either the term "CMS Approved" or the term "File & Use," as appropriate, with a placeholder for the date (i.e., two digits each for month and day, followed by a four digit year.) (For example "Y1234_drugx38 CMS Approved MMDDYYYY.") An actual date should not be included in the material ID when submitted. The unique material ID must be printed on the front page of all materials, including the SB and ANOC/EOC. The ID should be positioned in the lower left or right hand corner on the front page of the material and be in twelve (12)-point font.

PDPs and MA-PD plans must include the CMS contract number and PBP number on the membership identification card, as well as other required information as outlined in the Medicare Marketing Guidelines. The marketing material ID is, therefore not needed on the member ID card. Additionally, television and radio ads, outdoor advertisements, and banner or banner-like ads (including Internet banner ads) are not required to include the material ID. All

other materials should have the material ID which includes the placeholder for a CMS approval or File & Use date.

Use of the number of (i.e., H, R, or S) will allow the plan sponsor to submit marketing material that applies to only one contract while use of the MCE identifier of (Y) will allow the plan sponsor to submit marketing material that applies to multiple contract numbers. When submitting material using the MCE identifier, plan sponsors are not required to include the individual contract numbers in the material ID to which the material applies. Refer to § 90.15 contains additional guidance on the MCEs.

After the material is approved, accepted for File & Use, or deemed approved, the plan sponsors should enter the actual date on the material. The approval date should be the date that appears in HPMS with an approved status and the File & Use date should be the date the material is eligible for use in the market place (generally five (5) days after the piece is filed in HPMS). Refer to § 90.3.3 for additional guidance on deemed materials. These dates should appear on the material as they do in HPMS (i.e., include month, day and year). If the material is deemed approved, the plan sponsor will change the term "CMS Approved" to "Deemed" on its material master copy/internal system and show the deemed date, which is obtained from HPMS. (For example,"H1234_0021 Deemed 03152010.") The plan sponsor does not resubmit the material in HPMS solely to include the CMS approval, File & Use or deemed date.

40.1.1 - *Marketing Material Identification Number for Non-English or Alternate Materials*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264(e), 423.2264(e)

Non-English or alternate materials must *be given a unique material ID*. When submitting the materials, plan sponsors must utilize the proper dropdown menu in HPMS to designate that they are non-English versions. Refer to § *90.11 and* the HPMS Marketing Module User Guide for further guidance.

40.2 - Font Size Rule

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

All text included on materials, including footnotes, and internal tracking numbers, must be printed with a font size equivalent to or larger than Times New Roman twelve (12)-point*. The equivalency standard applies to both the height and width of the font.*

Exceptions:

- If a plan sponsor publishes a notice to close enrollment in the Public Notices section of a newspaper, the plan sponsor need not use twelve (12)-point font and can instead use the font normally used by the newspaper for its Public Notices section.

- Because neither CMS nor the plan sponsor has any control over the actual screen size shown on individuals' computer screens that can be adjusted by the user, for Internet marketing materials, the twelve (12)-point font requirement refers to how the plan sponsor codes the font for the Web page, not how it actually appears on the user's screen.

- Television Ads

40.3 - Footnote Placement

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

Plan sponsors should adopt a standard procedure for footnote placement. Footnotes should appear either at the end of the document or the bottom of each page and in the same place throughout the document. For example, the plan sponsor **cannot** include a footnote at the bottom of page 2 and then reference this footnote on page 8; the footnote must also appear at the bottom of page 8.

40.4 - Reference to Studies or Statistical Data

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

Plan sponsors may refer to the results of studies or statistical data in relation to customer satisfaction, quality, or cost as long as specific study details are given. At a minimum, study details need to be included in the material (either in the text or as a footnote) along with the source and date. Upon submitting material to CMS for review, the plan sponsor must provide to CMS the study sample size and number of plans surveyed unless the study that is referenced is a CMS study. Plan sponsors should enter study comments in the HPMS marketing material transmittal comments section.

- *Plan sponsors may distribute a study or statistical data (for example, Medicare Prescription Drug Plan Finder information) to directly compare their plan to another plan* in marketing materials to potential enrollees.
- If a plan sponsor uses study data that includes aggregate marketplace information on several other plans, it will not be required to submit data on all plan sponsors included in the study. However, the study details, such as the number of plans included, must be disclosed.

- Plan sponsors referencing a CMS study should include reference information (publication, date, page number) in the HPMS Marketing Material Transmittal comments field. For non-CMS sponsored studies, plan sponsors are to submit the sample and number of plans surveyed in the HPMS marketing material transmittal comments. Plan sponsors are prohibited from using CMS, Medicare, or the Department of Health & Human Services (DHHS) logos, even when referencing a CMS study.
- Additional information may be requested by the Account Manager or CMS marketing reviewer to help in facilitate the review of submitted materials.

40.5 - Prohibited Terminology/Statements

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

To ensure accurate and fair marketing by all plan sponsors, CMS prohibits the distribution of marketing materials that are materially inaccurate, misleading, or otherwise make material misrepresentations.

Plan sponsors may not:

- Misrepresent themselves, their plans, or the benefits and services covered by their plans.
- Claim within their marketing materials that they are recommended or endorsed by CMS, Medicare, or the Department of Health & Human Services (DHHS). Section 1140 of the Social Security Act, 42 U.S.C. §1320b-10, prohibits the use of the Department's name and logo, the agency's name and marks, and the word "Medicare" or "Medicaid" in a manner which would convey the false impression that such item is approved, endorsed, or authorized by CMS or DHHS, or that such person has some connection with, or authorization from, CMS or DHHS.
- Use absolute superlatives (e.g., "the best," "highest ranked," "rated number 1") unless they are substantiated with supporting data provided to CMS as a part of the marketing review process.
- Compare their organization/plan(s) to another organization/plan(s) by name unless they have written concurrence from all plan sponsors being compared *(for example, studies or statistical data as described in § 40.4)*. This documentation must be included when the material is submitted for review.

Plan sponsors may:

- State that the plan sponsor is approved for participation in Medicare programs and/or that it is contracted to administer Medicare benefits.

- Use the term “Medicare-approved” to describe their benefits and services within their marketing materials.

- Use qualified superlatives (e.g., “one of the best,” “among the highest rank”).

40.6 - Statements Related to Claim Forms and Paperwork

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

If a piece of material addresses the issue of claim forms or paperwork, plan sponsors may indicate that their plan involves relatively little paperwork such as:

- Virtually no paperwork

- Hardly any paperwork.

Given the nature of the Part C and D program it would be misleading to suggest that there are no forms or paperwork involved. Plan sponsors **cannot** say:

- No paperwork

- No claims or paperwork / no complicated paperwork

- No claim forms

40.7 - Logos/Tag Lines

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268(o), 423.2268(o)

The guidelines regarding the use of unsubstantiated statements that apply to advertising materials do not apply to logos/tag lines. Plan sponsors may use unsubstantiated statements in their logos and in their product tag lines (e.g., “Your health is our major concern,” “Quality care is our pledge to you,” “XYZ plan means quality care”). This latitude is allowed only in logo/product tag line language. Such unsubstantiated claims **cannot** be used in general advertising text regardless of the communication media employed to distribute the message. Notwithstanding the ability to use unsubstantiated statements as indicated above, the use of superlatives is not permitted in logos/product tag lines (e.g., “XYZ plan means the first in quality care” or “XYZ Plus means the best in managed care”).

40.8 - Identification of All Plans in Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

When plan sponsors submit multiple separate and distinct bids and PBPs to cover the same region/service area, there is no requirement that all Medicare plans offered by the plan sponsor be identified in all marketing materials. At their discretion, plan sponsors may identify or mention more than one plan in a single marketing piece so long as there is a distinction made *between plan type and benefits offered (if benefits are mentioned in the piece).*

40.9 - Marketing to Beneficiaries of Non-Renewing Medicare Plans

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

Plan sponsors may market directly to beneficiaries of former Medicare plans that have chosen not to renew their contracts as long as the marketing occurs after the date October 2, the latest date for beneficiary receipt of a plan sponsor's non-renewal letter.

40.10 - Product Endorsements/Testimonials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264, 422.2268, 423.2268

In order not to be considered misleading, product endorsements and testimonials must adhere to the following guidelines:

- *Content of product endorsements and testimonials, including statements by plan members must comply with the Medicare Marketing Guidelines.*
- The speaker must identify the plan sponsor's product by name.
- *A Medicare beneficiary may offer endorsement of a plan or promote a specific product, provided the individual is a current member of the plan being endorsed or promoted. If the individual is paid to endorse or promote the plan or product, this must be clearly stated (e.g., "paid endorsement").*
- *If an individual, such as an actor, is paid to portray a real or fictitious situation, the ad must clearly state it is a "Paid Actor Portrayal."*

- *Product endorsements a*nd testimonials cannot:
    - Use *any* quotes, *including* anonymous or fictitious quotes, by physicians, health care providers, and/or by Medicare beneficiaries not enrolled in the plan.
    - *Use negative testimonials about other plans.*

CMS may ask for a list of testimonials and release forms prior to reviewing/approving a material and plan sponsors are expected to comply with any requests for such information.

40.11 - Customer Service Call Center Hours of Operation

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.112(a)(7)(i) & (ii), 423.128(d)

A plan sponsor must list the hours of operation for its customer service call center in all places where a customer service number is provided for current and prospective enrollees to call (ID cards are excluded from this requirement). Refer to § 80.1 for additional guidance. The toll-free number must be a national toll-free number. Plan sponsors must also list the hours of operation for 1-800-MEDICARE any time the 1-800-MEDICARE number or Medicare TTY is listed (e.g., 24 hours a day/7 days a week).

40.11.1 - *Agent Broker Phone Number*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.112(a)(7)(i) & (ii), 423.128(d)

Advertisements that include an agent/broker's phone number should clearly indicate that calling the agent/broker number will direct an individual to a licensed insurance agent/broker. If an agent/broker phone number is listed then the plan sponsor's customer service phone number must also be included and all requirements regarding the customer service number in these Marketing Guidelines must be met (e.g., hours of operation, etc).

40.12 - Use of TTY Numbers

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 501 and Section 504 of the Rehabilitation Act

The TTY numbers must appear in conjunction with any other phone numbers in the same font size and style as the other phone numbers. Plan sponsors can either use their own TTY number

or State relay services, as long as the number included is accessible from TTY equipment. TTY customer service numbers must be toll-free.

Exceptions:

- TTY numbers need not be included on ODA or banner/banner-like ads.
- In television ads, the TTY number need not be the same font size/style as other phone numbers since it may result in confusion and cause some prospective enrollees to call the wrong phone number. As an alternative, plan sponsors are allowed to use various techniques to sharpen the differences between TTY and other phone numbers on a television ad (such as using a smaller font size for the TTY number than for the other phone numbers).
- TTY numbers are not required in radio or internet ads.

40.13 - Additional Materials Enclosed with Required Post Enrollment Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111, 423.128

Plan sponsors are permitted to enclose certain additional materials as part of required post-enrollment material mailings (e.g., EOB, EOC, and ANOC) when the following specific requirements are met and followed. Any informational materials that are enclosed with the post-enrollment mailing must be:

- Related to benefit or plan operations as an enrollee in the plan (e.g., health education newsletters, Medication Therapy Management Program (MTMP) materials, and mail service forms for Part D drugs), and
- Distinctly separate (e.g., folded or different color pages) from the required document within the mailing envelope.

Additional materials enclosed in the post-enrollment mailing must not include advertising materials (for example, materials advertising additional products such as Medigap by the plan sponsor). In addition, materials must comply with all relevant laws and regulations, including the Federal and any State anti-kickback statute.

40.14 - Marketing of Multiple Lines of Business

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Plan sponsors may market other lines of business (both health-related and non health-related) in accordance with the *requirement of this* section, *as well as § 170.*

40.14.1 - *Multiple Lines of Business - General Information*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Plan sponsor marketing materials sent to current members describing other health-related lines of business must contain instructions describing how individuals may opt out of receiving such communications. Plan sponsors must make every effort to ensure that all individuals (including non-members) who ask to opt out of receiving future marketing communications are not sent such communications. For marketing multiple lines of business, plan sponsors must comply with the HIPAA rules outlined in § *40.14.5 and § 170 regarding use of beneficiary information.*

Plan sponsors that advertise multiple lines of business within the same marketing document must keep the organization's lines of business clearly and understandably distinct from the other products. Plan sponsors must make this distinction by utilizing different formatting styles that delineate the two products. For example, the document might highlight the name of the MA or PDP product in bold and underlined font, and then include a paragraph to describe the product in "regular" font, next go on to highlight the name of a non-MA/PDP product in bold and underlined font, and then include a paragraph describing the non-plan product in "regular" font. Also, if a plan sponsor advertises non-Medicare products with plan material, it must pro-rate any costs so that costs of marketing non-Medicare materials are not included as "plan-related" costs in the plan sponsor's bid to CMS.

40.14.2 - *Multiple Lines of Business - Exceptions*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Plan sponsors must ensure that all marketing activities conform to the guidance provided in this document with regard to marketing through unsolicited contacts (refer to § 70.4).

While plan sponsors may mention non-plan lines of health related products at the time they send a plan non-renewal notice, they may only do so using separate enclosures within the same envelope. Plan sponsors *are prohibited from* mentioning non-Medicare lines of business within the *interim and final* non-renewal notices *in order to ensure that the non-renewal notices give beneficiaries focused information only about the plan non-renewal.*

Plan sponsors must not include enrollment applications for competing lines of business (e.g., MA-PD or MA plans and Medigap products) or for other non-Medicare lines of business in mailings that combine plan information with other product information.

40.14.3 - Multiple Lines of Business – Television

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Plan sponsors may market other lines of business concurrently with plan products on television advertisements. However, they must ensure that non-plan products are separate and distinct from the plan products.

40.14.4 - *Multiple Lines of Business – Internet*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2260, 423.2260

Plan sponsors may market other lines of business concurrently with plan products on the Internet. *To avoid beneficiary confusion, plan sponsors must continue to maintain a separate and distinct section of their website for Medicare information only. CMS will review plan sponsors' web pages to ensure that plans are maintaining the separation between Part C, Cost and Part D product lines and information on other lines of business.*

40.14.5 - Multiple Lines of Business - HIPAA Privacy Rule

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

45 CFR 160

Generally, plan sponsors are not required to obtain authorization from enrollees to use or disclose an enrollee's protected health information with regard to providing communication about replacements of or enhancements to the plan sponsor's benefits or the plan sponsor's health-related value added products and services. These categories are exceptions to the definition of marketing in the HIPAA Privacy Rule. In complying with these exceptions, plan sponsors may use and disclose protected health information to make communications to enrollees about other lines of business provided by the covered entity.

However, plan sponsors must obtain authorization from an enrollee prior to using or disclosing the enrollee's protected health information for any marketing that does not fall within the exceptions to the definition of marketing under the HIPAA Privacy Rule. For example, enrollee authorization is needed if the product is a pass-through of a discount available to the public at large, such as an accident only policy, a life insurance policy, or an item or service that is not health-related.

40.14.6 - *Multiple Lines of Business - Non-Benefit/Service-Providing Third Party Marketing Materials*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

CMS does not review marketing materials originated by non-benefit/service-providing third party entities. A non-benefit/service-providing third party entity is an entity that contracts with a plan sponsor to perform responsibilities other than administering health care/prescription drug benefits or providing health care services/Part D drugs to Medicare beneficiaries. For the purpose of marketing review, non-benefit/service providing third party entities are organizations or individuals that supply information to Medicare beneficiaries or a plan sponsor's membership, which is paid for by the plan sponsor or the non-benefit/service-providing third party entity. An example of a non-benefit/service-providing third party could be a research firm that provides comparative data relating to Medicare Advantage /Part D plans or a company that provides electronic health records to providers or beneficiaries,

Therefore, if a non-benefit/service-providing third party wishes to develop and/or provide information to a plan sponsor's members, it must submit its materials to the plan sponsor, which in turn, may distribute the materials to its membership. The plan sponsor must ensure that the following disclaimer is placed on the material given that CMS does not review these materials:

> *"Medicare has neither reviewed, nor endorsed, this information."*

This disclaimer must be prominently displayed at the bottom center of the first page of the material and must be of the same font size and style as the commercial message.

Plan sponsors utilizing third parties for telephone calls to plan enrollees must adhere to all guidance in § 70.5.1.

40.15 - Providing Materials in Alternate Formats/Media Types

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.64, 422.111, 423.48, and 423.128; Social Security Act [§1852(c) (1) and §1860D-4(a)(1)(A)]

The Social Security Act (§1852(c)(1) and §1860D-4(a)(1)(A)) and Medicare regulations describe how information must be provided to beneficiaries (in a clear, accurate, and standardized form, but do not limit the methods of transmittal. Refer to § 50.1.6 for additional information on alternate formats.

As such, a plan sponsor may elect to provide materials to members or prospective members in a format other than traditional paper (e-mail, CD, DVD). With respect to materials that CMS

deems mandatory, (the SB, ANOC, EOC, the provider/pharmacy directory, *Part D Explanation of Benefits, and the Model Part D Transition Letter*), plan sponsors have the option of contacting members to determine in what format they would like to receive the materials. Plan sponsors that choose this option must either contact members in writing (e.g., by letter, postcard, newsletter article**,** *secure website*) or via a recorded telephone conversation to determine whether they would like to receive a specific material or group of materials in another format. The plan sponsor must specify to the member the materials in question. If the plan sponsor does not receive a response from the member, then the plan sponsor must assume that the member wants to receive the information in hard copy. CMS may review plan electronic communication and portable media policies, procedures, systems, and documentation during monitoring and compliance visits.

In addition, plans electing to provide ***any*** materials in an alternate format must:

- *Provide hard copies of all member materials available to members upon request (Note that requests for hard copies of plan web pages are excluded from this requirement.)*

- Ensure that the process is completely voluntary. Members must be informed of the option and be given the choice to opt-in. If a member no longer wishes to receive plan communications through electronic or portable media, they must be able to opt-out upon request.

- Document each member's election *(opt-in**)*** to receive plan communications either electronically (alternate format) or other portable media formats.

- Have safeguards in place to ensure that member contact information is current, communication materials are delivered and received timely and appropriately, and important materials are identified in a way that members understand their importance.

- Have a process for automatic mailing of hard copies when electronic versions are undeliverable (for example an expired e-mail account).

- Have a system in place to monitor and evaluate the effectiveness of the electronic communication process.

Finally, if a plan elects to distribute plan information to members through electronic media (e.g., e-mails) instead of providing hard copies (paper), the plan is responsible for ensuring that it is in compliance with HIPAA.

40.16 - Standardization of Plan Name Type

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268 (q), 423.2268 (q), section 1851 (a)(6) of the Act

Plan sponsors must include the plan type in each plan's name using standard terminology as developed by the Secretary. Plan sponsors enter and maintain their plan names in the HPMS. The plan name is used by internal CMS systems and in standardized marketing tools, including, but not limited to the SB, Medicare Options Compare and Medicare Prescription Drug Plan Finder on http://www.medicare.gov, and the Medicare & You Handbook.

To ensure the consistent use of standardized plan type terminology across all plan sponsors, HPMS auto-populates the plan type label at the end of each plan name. For instance, an HMO plan named "Golden Medicare Plan" would appear as follows: "Golden Medicare Plan (HMO)." The auto-generated plan type label will not count toward the fifty (50) character maximum length reserved for the plan name field.

In addition to standardizing the terminology in HPMS, plan sponsors must display the plan type *on all marketing materials, including plan logos.* Plans that have previously incorporated the plan type in their plan names in a position other than at the end of the plan name must now place the plan *type* at the end on printed marketing materials.

The following exceptions to the plan name requirements apply:

- *Plans are not required to include the parentheses with the plan type for materials that are not auto generated from HPMS. CMS will allow plan sponsors to either spell out the plan name type or abbreviate on materials that are not generated from HPMS. For example, use of either "Acme Medicare HMO" or "Acme Medicare Health Maintenance Organization."*
- Operational letters or logos that do not mention the plan name are not required to include the plan type.
- Communication information provided verbally to beneficiaries (e.g., scripts) does not require the plan type designation.
- *Plans* that have incorporated the plan type at the end of the plan name (e.g., Gold Plan PFFS) are not required to repeat the plan type in the plan name.
- *Inclusion of the plan type is not required throughout an entire document. However plans must include the plan type on the front page or at the beginning of the document. Model documents to which the only modification is the addition of the required plan name type will still be eligible for a ten (10) day review provided no other modifications are made to the document.*

NOTE: *Since 2010, HPMS has automatically appended all plan names with the standardized plan type label, described below. Starting in 2011, the standardized plan type label will also distinguish which plans are Special Needs Plans (SNPs).*

Please Note: Employer Group Waiver Plans (i.e., 800-series plans) will be appended with the standardized plan type labels below. There is no further distinction between 800-series plans and individual market plans.

The following table outlines the standardized plan type terminology to be generated for each active HPMS plan type.

Table 40.16.1 Standardized Plan Type Terminology

Standardized Plan Type Terminology	
Plan Type	**Plan Name with Standardized Plan Type Label**
HMO	Plan Name (HMO)
HMO SNP	Plan Name (HMO SNP)
PPO	Plan Name (PPO)
PPO SNP	Plan Name (PPO SNP)
HMO-POS	Plan Name (HMO-POS)
HMO-POS SNP	Plan Name (HMO-POS SNP)
ESRD II SNP	Plan Name (HMO-POS SNP)
PSO	Plan Name (PSO)
PSO SNP	Plan Name (PSO SNP)
MSA	Plan Name (MSA)
MSA Demo	Plan Name (MSA)
RFB PFFS	Plan Name (PFFS)
PFFS	Plan Name (PFFS)
ESRD I	Plan Name (PFFS)
1876 Cost	Plan Name (Cost)
1833 Cost	Plan Name (Cost)
PDP	Plan Name (PDP)
Regional PPO	Plan Name (Regional PPO)
Regional PPO SNP	Plan Name (Regional PPO SNP)
Employer PDP	Plan Name (Employer PDP)
Employer PFFS	Plan Name (Employer PFFS)
RFB HMO	Plan Name (HMO)
RFB HMO-POS	Plan Name (HMO-POS)
RFB Local PPO	Plan Name (PPO)
RFB PSO	Plan Name (PSO)
CCRC	Plan Name (HMO-POS)
CCRC SNP	Plan Name (HMO-POS SNP)

50 - *Marketing Material Types and Applicable Disclaimers*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

In general, CMS groups marketing materials into two distinct categories – advertising and explanatory marketing materials. Unless noted otherwise, the following disclaimers must be present on all advertising and explanatory materials as directed.

Please note that if the document is a model document and the CMS model does not include the disclaimer, the disclaimers are not required until the model is updated. If plan sponsors choose to include the disclaimers provided in this guidance on model documents, this is considered a model without modification and therefore can be submitted for a ten (10)-day review. If plan sponsors submit a model document and modify and/or revise the disclaimers provided in this guidance, the material should be submitted for a forty-five (45)-day review. Documents that are standardized (e.g., the SB) should not include the following disclaimers unless they are already present on the standardized document.

For all materials, disclaimers must be prominently displayed on the material and must be of the similar font size and style (refer to § 40.2 and § 40.3 for more information).

In addition to the guidance provided in this section, materials must also comply with the other requirements and responsibilities provided in these *Medicare Marketing* Guidelines.

50.1 - Guidance and Disclaimers Applicable to Advertising Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

Advertising materials generally contain less detail than explanatory marketing materials. Advertising materials may provide basic benefit information to entice a potential enrollee to request information. As a general rule, materials that contain basic benefit information are considered advertising. Although not an exhaustive listing, some examples of advertising materials include:

- *Banner and banner-like ads;*
- *Direct mail*
- *Counter tents;*
- *Event signage;*
- *Internet advertising;*
- *Outdoor advertising;*
- *Pharmacists' promotional buttons:*

- *Post stands;*
- *Print ads;*
- *Radio ads;*
- *Television ads; and*
- *Window stickers.*

The following disclaimers are applicable to advertising materials. It is the responsibility of the plan sponsor to ensure it meets all requirements contained within the referenced sections as well as any additional disclaimer requirements throughout § 50 related to specific materials or plan types (e.g., SNP, PFFS, invitations to events).

- *Federal Contracting Statement – § 50.1.2*
- *Disclaimers When Benefits Are Mentioned (if applicable) – § 50.1.3*
- *Disclaimers for the Marketing of Educational Events (if applicable) – § 50.1.7*
- *Disclaimers on Advertisements and Invitations to Sales/Marketing (if applicable) – § 50.1.8*
- *Disclaimers on Advertising that Promotes a Nominal Gift (if applicable) – § 50.1.9*
- *Disclaimer for Third Party Marketing Materials (if applicable) – § 50.1.13*

50.1.1 - *Guidance and Disclaimers Applicable to Explanatory Materials*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

In general, explanatory marketing materials include those materials that are sent to prospective members prior to enrolling (enrollment) and to current and new members as part of their enrollment (post-enrollment). Explanatory materials include a higher level of detail with regard to plan benefits and costs. As a general rule, materials that contain a high level of detail (such as premiums, cost-sharing, detailed plan brochure, ANOC/EOC) are subject to all explanatory disclaimers and submission requirements.

The following disclaimers are applicable to explanatory materials. It is the responsibility of the plan sponsor to ensure they meet all requirements contained within the referenced sections as well as any additional disclaimer requirements throughout § 50 related to specific materials or plan types (e.g., SNP, PFFS, PPO, and co-branding materials).

- *Federal Contracting Statement – § 50.1.2*
- *Disclaimers When Benefits Are Mentioned – § 50.1.3*
- *Disclaimers on Materials that Mention Plan Benefit and Premium Information - § 50.1.4*
- *Information on Enrollment Limitations – § 50.1.5*
- *Availability of Alternate Format – § 50.1.6*

The bullets below outline additional disclaimers based on specific materials or plan types. They are included in this guidance as a reference tool for plans and reviewers but should not be

considered an exhaustive list. It is the responsibility of the plan sponsor to ensure all disclaimers and requirements throughout § 50 are contained within the appropriate materials.

- *Part D sponsors materials mentioning Part D benefits must also indicate: "You may be able to get Extra Help to pay for your prescription drug premiums and costs. To see if you qualify for Extra Help, call: 1-800-MEDICARE (1800-633-4227). TTY users should call 1-877-486-2048, 24 hours a day/ 7 days a week; the Social Security Office at 1-800-772-1213 between 7 a.m. and 7 p.m., Monday through Friday. TTY users should call, 1-800-325-0778; or Your Medicaid Office (only required for pieces referencing Part D benefits or cost-sharing)". (§ 50.1.4)*

- *MA and MA-PD plans must also insert: "Individuals must have both Part A and Part B to enroll." (§ 50.1.5)*

- *Materials for marketing of education events must also include: "This event is only for educational purposes and no plan-specific benefits or details will be shared." (§ 50.1.7)*

- *Invitations to sales/marketing events must also insert: "A licensed, authorized representative will be present with information and applications. For accommodation of persons with special needs at sales meetings, call <insert phone, TTY, and hours of operation>." (§ 50.1.8)*

- *Materials promoting nominal gifts must also insert a written statement on all materials advertising/promoting drawings, prizes or any promise of a free gift that there is no obligation to enroll in the plan. (§ 50.1.9)*

- *Part D sponsor materials mentioning Part D benefits must also include a statement indicating that in general, beneficiaries must use network pharmacies to access their prescription drug benefit, except in non-routine circumstances, and quantity limitations and restrictions may apply. (§ 50.1.10)*

- *MA and MA-PD plans whose members are locked into a provider network must also insert information that the member must receive all routine care from plan providers. (§ 50.1.11)*

- *Materials that are co-branded with providers must also insert" Other <pharmacies/physicians/providers> are available in our network." (§ 50.1.12)*

- *Third-party materials must also include a disclaimer noting "Medicare has neither reviewed nor endorsed this information." (§ 50.1.13)*

- *PPO plans must also insert information that it may cost more to get care from out-of-network providers, except in an emergency. (§ 50.1.14)*

- *Section 1876 cost plans must insert information on premium and cost-sharing for services received through the plan and optional supplemental benefit packages. (§*

50.1.15)

- *Non-network PFFS plans must also insert: "A Medicare Advantage Private Fee-for-Service plan works differently than a Medicare supplement plan. Your provider is not required to agree to accept the plan's terms and conditions, and thus may choose not to treat you, with the exception of emergencies. If your provider does not agree to accept our payment terms and conditions of payment, they may choose not to provide health care services to you, except in emergencies. If this happens, you will need to find another provider that will accept our payment terms and conditions. Providers can find the plan's terms and conditions on our website at: [insert link to PFFS terms and conditions]." If the material is part of an enrollment kit it must also contain a leaflet for provider education on plan rules and information. (§ 50.1.16)*

- *Full and partial network PFFS plans must also insert: "A Medicare Advantage Private Fee-for-Service plan works differently than a Medicare supplement plan. We have network providers (that is, providers who have signed contracts with our plan) for [[full network PFFS plan insert: all services covered under Original Medicare][partial network PFFS plans should indicate the category or categories of services for which network providers are available]]. These providers have already agreed to see members of our plan. If your provider is not one of our network providers, then the provider is not required to agree to accept the plan's terms and conditions, and thus may choose not to treat you, with the exception of emergencies. If your provider does not agree to accept our payment terms and conditions, they may choose not to provide health care services to you, except in emergencies. If this happens, you will need to find another provider that will accept our payment terms and conditions. Providers can find the plan's terms and conditions on our website at: [insert link to PFFS terms and conditions]." If the material is part of a enrollment kit it must also contain a leaflet for provider education on plan rules and information. (§ 50.1.16)*

- *DE SNPs must also insert a statement that premiums, co-pays, co-insurance and deductibles may vary based on the level of help received. (§50.1.17)*

- *SNPs must also insert eligibility requirements for SNP enrollment (e.g., "This plan is available to anyone who meets the Skilled Nursing Facility (SNF) level of care and resides in a nursing home") on enrollment explanatory materials. (§ 50.1.18)*

50.1.2 - *Federal Contracting Statement*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

All advertising and explanatory materials must include the statement that the plan sponsor contracts with the Federal government. Exceptions include:

- *Banner and banner-like ads;*

- *Outdoor advertising; and*
- *Television and Internet banner ads*

At least one of the following statements must be used by MA or MA-PD plans as the contracting statement. The statements should not be modified and may be either in the text of the piece or at the end/bottom of the piece.

- *"A/An [insert plan type: HMO, PPO, PFFS POS plan, PSO] with a Medicare contract;"*
- *"A Medicare Advantage organization with a Medicare contract;"*
- *"A Health plan with a Medicare contract;"*
- *"A Federally-Qualified HMO with a Medicare contract;"*
- *"A Federally-Qualified Medicare contracting HMO;"*
- *"Medicare-approved [insert plan type: HMO, PPO, PFFS, POS plan, PSO, Cost, MSA];" or*
- *"A Coordinated Care plan with a Medicare Advantage contract."*

PDP sponsors must use one of the following contracting statements below. The statements may not be modified and may either be in the text of the piece or at the end/bottom center of the piece.

- *"A Federally-Qualified Medicare Contracting Prescription Drug Plan;"*
- *"A Medicare-approved Part D sponsor;" or*
- *"A stand-alone prescription drug plan with a Medicare contract."*

50.1.3 - *Disclaimers When Benefits Are Mentioned*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111(a), 422.111 (b), 422.111(f), 423.128(b)

Marketing materials may provide basic benefit information to entice a potential enrollee to request additional information. When benefit information is provided, the following disclaimer must be utilized on advertising and explanatory materials:

> *"The benefit information provided herein is a brief summary, not a comprehensive description of benefits. For more information contact the plan."*

Additionally, plan sponsors must include a statement in their current contracting year marketing materials (advertising and explanatory) when advertising a current year benefit, formulary, pharmacy network, premium, or co-payment that such information may change in the upcoming contracting year.

Model disclaimer:

> *"[Benefits, formulary, pharmacy network, premium and/or co-payments/co-insurance] may change on January 1, <XXXX>."*

Exception: The benefit change disclaimer does not need to be included within the text of enrollment forms.

50.1.4 - *Explanatory Materials that Mention Plan Benefit and Premium Information*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111(a)(2), 422.2264, 423.128(a)(2), 423.2264

Explanatory materials for all plan sponsors that describe benefit and plan premium information must:

- *Include a disclaimer stating "You must continue to pay your Medicare Part B premium." This disclaimer is not required if the Part B premium is entirely paid by rebates under the plan. This statement is required even if the plan premium is $0. Note that full-benefit DE SNPs for whose members the State pays the Part B premium should indicate that the Part B premium is covered for full-dual members.*

- *Indicate that limitations, copayments, and restrictions may apply.*

- *Part D sponsors must include the following in all explanatory materials that reference Part D premiums or other costs for Part D. Plans may include the following language in paragraph or bullet form if the plan sponsor is sending out an individual letter:*

  "You may be able to get Extra Help to pay for your prescription drug premiums and costs. To see if you qualify for extra help, call:
  - *1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048, 24 hours a day/7 days a week;*
  - *The Social Security Office at 1-800-772-1213 between 7 a.m. and 7 p.m., Monday through Friday. TTY users should call, 1-800-325-0778; or*
  - *Your State Medicaid Office."*

In addition, CMS encourages plans to insert the following on all enrollment materials that include Part D benefit and premium information:

> *"People with limited incomes may qualify for Extra Help to pay for their prescription drug costs. If eligible, Medicare could pay for up to one hundred (100) percent of drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify will not be subject to the coverage gap or a late enrollment penalty. Many people are eligible for these savings and don't even know it. For more information about this Extra Help, contact your local Social Security office or call 1-800-MEDICARE (1-800-633-4227), 24 hours per day, 7 days per week. TTY users should call 1-877-486-2048."*

50.1.5 - *Information on Enrollment Limitations*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

Plans must indicate on all enrollment explanatory materials that members may enroll in a plan only during specific times of the year. Plans may either describe all enrollment periods in detail or refer individuals to the customer service department for more information. For example:

> *"Members may enroll in the plan only during specific times of the year. Contact <plan> for more information."*
>
> *Exception: Section 1876 cost plans not offering Part D benefits, DE SNPs, and Institutional SNPs (I-SNPs), should indicate that eligible beneficiaries can enroll at any time. Section 1876 cost plans should indicate that eligible beneficiaries can enroll at any time but may elect the Part D optional supplemental benefit, if offered, only during specific times of the year. Additionally MA and MA-PD plans must also include a statement on explanatory materials that individuals must have Part A and Part B to enroll in the plan.*

50.1.6 - *Availability of Alternate Formats*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

Plan sponsors must provide a disclosure on all explanatory marketing materials including:

- *A statement that the document is available in alternate formats or languages;*
- *A phone number the beneficiary can call for the information in other formats or languages; and*
- *A translated alternative format disclaimer in any non-English language that meets the ten percent threshold for a PBP service area. The translated disclaimer should be placed below the English version and in the same font size as the English version.*

> ***NOTE:*** *ID cards are excluded from this requirement*

50.1.7 - *Applicable Disclaimers for the Marketing of Educational Events*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

CMS requires use of the following disclaimer on all announcements (advertising and explanatory) when an educational event is organized, sponsored or promoted by a plan sponsor.

> *"This event is only for educational purposes and no plan-specific benefits or details will be shared."*

This disclaimer is not required when a plan sponsor is invited to be a participant in an educational event sponsored, organized or promoted by an entity other than the plan sponsor.

50.1.8 - *Disclaimer on Advertisements and Invitations to Sales/Marketing Events*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

Advertisements and invitations to Sales/Marketing events (in any form of media) that are used to invite beneficiaries to attend a group session with the possibility of enrolling those individuals must include the following two statements on advertising and explanatory materials:

- *"A sales person will be present with information and applications."*
- *"For accommodation of persons with special needs at sales meetings call <insert phone and TTY number>."*

Such invitations must also clearly state all of the products that will be discussed during the event (i.e. HMO, PDP).

50.1.9 - *Disclaimers Applicable to Advertising that Promotes a Nominal Gift*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268(b), 423.2268(b)

Plans must include a written statement on all advertising and explanatory materials promoting drawings, prizes or any promise of a free gift that there is no obligation to enroll in the plan. For example:

- *"Eligible for a free drawing and prizes with no obligation."*
- *"Free drawing without obligation."*

For additional information on nominal gifts, refer to § 70.2.

50.1.10 - *Pharmacy Network Limitations*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.120

All plan sponsors offering Part D benefits must include a statement on all explanatory marketing materials that indicates eligible beneficiaries must use network pharmacies to access their prescription drug benefit, except under non-routine circumstances, and quantity limitations and restrictions may apply.

50.1.11 - *Required Access Information Disclaimers*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

One of the following statements is required on all enrollment explanatory materials used by all MA and MA-PD plans whose members are locked into a provider network (if the member obtains routine care from an out-of-network provider, neither the plan nor Original Medicare will be responsible for the cost of care):

- *For materials of short length (in general, materials 1 page [front and back] and shorter are considered to be of short length): "You must receive all routine care from plan providers."*

- *In all other written materials: "You must use plan providers except in emergency or urgent care situations <<or for out-of-area renal dialysis or other services.>> If you obtain routine care from out-of-network providers neither Medicare nor <plan name> will be responsible for the costs."*

50.1.12 - *Disclaimer for Materials that are Co-branded with Providers*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Plan sponsors that choose to enter into co-branding relationships with network providers are required to include all co-branded provider names and/or logos on explanatory marketing materials related to the members' selection of specific providers or provider organizations (e.g., physicians, hospitals). Refer to 30.2 for additional information on co-branding. Co-branding marketing materials are required to include the following disclaimer:

"Other <Pharmacies/Physicians/Providers> are Available in Our Network."

50.1.13 - *Disclaimer When Providing Third Party Marketing Materials*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

CMS does not review marketing materials originated by non-benefit/service-providing third-party entities. Therefore, if a non-benefit/service-providing third party wishes to market to a plan sponsor's members, it must submit its materials to the plan sponsor which, in turn, may distribute the materials to its membership. An example of this is a third party entity that develops and creates plan comparison documents which are sent to the plan sponsor's members, with the plan sponsor's approval. In this example, either the plan sponsor or third party may distribute the document to the members. It is the plan sponsor's responsibility to ensure that advertising and explanatory materials contain the disclaimer:

"Medicare has neither reviewed nor endorsed this information."

This disclaimer must be prominently displayed at the bottom center of the first page of the material and be in the similar font size and style as the message.

50.1.14 - *Additional Guidance for Preferred Provider Organization (PPO) and Point of Service Plans (POS)*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

In addition to the applicable requirements and disclaimers noted in § 50, explanatory materials must include information that, with the exception of emergencies or urgent care, it may cost more to get care from out-of-network providers.

50.1.15 - *Additional Guidance for Section1876 Cost Plans*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

In addition to the applicable requirements and disclaimers noted in § 50, the following guidance is applicable to 1876 cost plans. Section 1876 cost plans must describe in their explanatory marketing materials the premiums and cost-sharing for services received through the section 1876 cost plan, and any optional supplemental benefit packages they offer. They must also

indicate that premiums, cost-sharing, and optional supplemental benefits may change each year, and include information on when such benefit options may be selected or discontinued.

All post-enrollment materials must clearly explain that members may use plan and non-plan providers, and also explain the benefit/cost-sharing differentials between use of plan and non-plan providers.

50.1.16 - *Additional Guidance Applicable to All PFFS Plan Materials*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

In addition to the applicable requirements and disclaimers noted in § 50 the following guidance is applicable to PFFS plans.

The following PFFS disclaimer must be prominently displayed within all enrollment explanatory materials including, but not limited to websites and materials used at sales presentations by agents/brokers (employed and contracted).

- *For non-network PFFS plans: "A Medicare Advantage Private Fee-for-Service plan works differently than a Medicare supplement plan. Your provider is not required to agree to accept the plan's terms and conditions of payment, and thus may choose not to treat you, with the exception of emergencies. If your provider does not agree to accept our terms and conditions of payment, they may choose not to provide health care services to you, except in emergencies. If this happens, you will need to find another provider that will accept our terms and conditions of payment. Providers can find the plan's terms and conditions of payment on our website at: [insert link to PFFS terms and conditions of payment]."*

- *For full and partial network PFFS plans: "A Medicare Advantage Private Fee-for-Service plan works differently than a Medicare supplement plan. We have network providers (that is, providers who have signed contracts with our plan) for [[full network PFFS plan insert: all services covered under Original Medicare][partial network PFFS plans should indicate the category or categories of services for which network providers are available]]. These providers have already agreed to see members of our plan. If your provider is not one of our network providers, then the provider is not required to agree to accept the plan's terms and conditions, of payment, they may choose not to provide health care services to you, except in emergencies. If this happens, you will need to find another provider that will accept our terms and conditions of payment. Providers can find the plan's terms and conditions of payment on our website at: [insert link to PFFS terms and conditions of payment]."*

All marketing representatives selling PFFS plans are required to verbally read or state this disclaimer during sales presentations in public venues and private meetings with beneficiaries.

PFFS plans are prohibited from using any materials or making any presentations that imply PFFS plans function as Medicare supplement plans or use terms such as "Medicare Supplement replacement." MA organizations may not describe PFFS plans as plans that cover expenses that Original Medicare does not cover nor as plans that offer Medicare supplemental benefits. However, it is permissible for PFFS plans to clarify that the plan does not pay after Medicare pays its share; rather, it pays instead of Medicare and the beneficiary pays any applicable cost-share or co-pay.

Model language is provided to incorporate into sales presentations describing the special aspects of PFFS plans which differ from supplements and other MA plans (refer to http://www.cms.hhs.gov/PrivateFeeforServicePlans/). PFFS plans should refer to the above web link for additional information on the inclusion of balance billing notification in the EOC.

Additionally, enrollment kits for PFFS plans must provide enrollees with a complete description of plan rules detailing information on a provider's choice whether to accept the plan's terms and conditions of payment. CMS has developed a model document that beneficiaries may show their health care provider for this purpose (refer to http://www.cms.hhs.gov/PrivateFeeforServicePlans/).

The leaflet must be included in all enrollment kits that prospective enrollees receive and must be available on the PFFS plan sponsor's website. The leaflet must be submitted to CMS using the File & Use certification process.

50.1.17 - *Additional Guidance for Dual Eligible SNP Materials*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2, 422.4(a)(1)(iv), 422.111(b)(2)(iii), 422.2264, 423.2264

For each contract year, plan sponsors offering Dual-Eligible SNPs (DE SNP) must provide each prospective enrollee, prior to enrollment, with a comprehensive written statement of benefits and cost-sharing protections under the SNP as compared to protections under the relevant State Medicaid plan. The written statement should be provided in the form of a SB that includes Section IV. DE SNPs may not impose cost-sharing requirements on specified dual-eligible individuals that would exceed the amounts permitted under the State Medicaid plan if the individual were not enrolled in the DE SNP. This requirement will assist a prospective dual-eligible enrollee in determining if he/she will receive any value from enrolling in the DE SNP that is not already available under the State Medicaid program.

Marketing materials that discuss or mention DE SNP information must also include a statement in explanatory materials that [premiums],[co-pays],[co-insurance], and [deductibles] may vary based on the level of Extra Help that beneficiaries may receive, and that the beneficiary should contact the plan for further details.

50.1.18 - *Additional Guidance for SNP Materials*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2, 422.4(a)(1)(iv), 422.111(b)(2)(iii), 422.2264, 423.2264

Plan sponsors must include the eligibility requirements for SNP enrollment on enrollment explanatory materials. Some examples are:

- *"This plan is available to anyone who meets the Skilled Nursing Facility (SNF) level of care and resides in a nursing home."*
- *"This plan is available to all people with Medicare who have been diagnosed with HIV/AIDS."*
- *"This plan is available to anyone who has both Medical Assistance from the State and Medicare."*

50.1.19 - *Radio Advertisements*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

Radio advertisements for a plan sponsor must include the plan sponsor's toll-free number and applicable requirements for hours of operation. Additionally, any radio ads that mention benefit information must state the general advertising disclaimer noted in § 50.1.3. The Federal contracting statement is not required. Radio advertisements are File & Use eligible documents.

50.1.20 - *Television Advertisements*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

Television advertisements for a plan sponsor must include the plan sponsor's toll-free number and applicable requirements for hours of operation. Additionally, any television ads that mention benefit information must contain the general advertising disclaimer noted in § 50.1.3. This information must be displayed on the crawl or banner. The Federal contracting statement is not required; however, any other required disclaimers (e.g., actor portrayal) must be worked into the script and/or shown on the screen. Television advertisements are File & Use eligible documents.

50.1.21 - *Online Enrollment Center Disclaimers for Websites*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

With a few exceptions, outlined below, all plan sponsors must accept enrollment in a plan through the Online Enrollment Center (OEC). The OEC is accessible through http://www.medicare.gov.

Plans accepting enrollment requests through the OEC, must state the following disclaimer on their websites:

> *"Medicare beneficiaries may enroll in <plan name> through the CMS Medicare Online Enrollment Center located at http://www.medicare.gov."*

NOTE: *There are few exceptions for certain plan types that are not required to or cannot accept enrollment through the OEC. These plan types include section1876 cost plans, Medicare Savings Account (MSA) plans, and 800 series employer group waiver plans. SNPs and Religious Fraternal Benefit plans may but are not required to accept enrollment through the OEC.*

50.1.22 *Enrollment and Marketing Materials after Non-Renewal or Service Area Reduction (SAR) Notice to CMS*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.

Enrollment and marketing materials must prominently announce to prospective enrollees the decision to non-renew or reduce the service area. For efficient operation of the program, plan sponsors that are non-renewing or reducing their service area should cease marketing of the non-renewed/reduced plan(s) after August 31st. The following is model language that may be used as an attachment or addendum or in a script for customer service representatives.

> *< Insert plan sponsor name> will [(not be renewing its Medicare contract) or (will not be serving the following areas) effective January 1, <Upcoming Year> or [will not be offering individual beneficiary coverage]. You may choose to enroll in our plan, but your coverage will automatically end on December 31, <Current Year>, (insert, if appropriate <areas plan sponsor will not be serving>). You are also entitled to enroll in a new MA-PD plan, section 1876 cost or PDP beginning October 1 through December 31, <Current Year>. If you do not enroll in another MA-PD plan, section 1876 cost plan or PDP plan effective January 1, <Upcoming Year>, you will be disenrolled from the*

plan on this date. You will receive additional information in the fall about your rights and additional options.

50.2 - Plan Sponsor Mailing Statements

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2272(b), 423.2272(b)

In order to ensure that beneficiaries can quickly and easily identify the contents of a plan sponsor's mailing, all plan sponsors that mail information to prospective or current Medicare beneficiaries should prominently display one of the following four statements on the front of the envelope or the mailing itself (if no envelope is being sent). Plan sponsors are permitted to meet this requirement through the use of ink stamps or stickers if necessary, in lieu of pre-printed statements. Any delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a plan sponsor must comply with this requirement.

1. *Advertising pieces – "This is an advertisement"*
2. *Plan information – "Important plan information"*
3. *Health and wellness information – "Health or wellness or prevention information"*
4. *Non-health or non-plan information - "Non-health or non-plan related information"*

All mailings should include one of these four mailing statements. If a mailing is not advertising or a health and wellness mailing, but is related to an enrollee's plan, plan sponsors should categorize it as a plan information mailing. However, if the mailing contains non-health or non-plan related information (refer to § 170.2 for examples), a plan sponsor should use the "non-health or non-plan related information" mailing statement. Plan sponsors may not modify these mailing statements and must use them verbatim. In addition, plan sponsor are not permitted to create additional mailing categories and/or statements.

Mailing statements should only be placed on the mailing when no envelope accompanies the mailer (e.g., tri-fold brochure or postcard). Plan sponsors may place one of the four statements on the mailing so that they are visible from the window of the envelope (as opposed to on the outside of the envelope) only if the disclaimer is prominently displayed within the display window of the envelope and is separate and distinct from the beneficiary's name/address.

CMS expects that all plan envelopes or mailings will include one of the four statements and that the statements will be prominently displayed so that beneficiaries can easily identify the content of the mailer. In addition, plan sponsors must ensure that their plan name or logo is included in every mailing to plan enrollees (either on the envelope or in the mailing when no envelope accompanies the mailer).

Plan sponsors should not create envelopes that look like they are being sent from an official government source (e.g., red, white & blue flags on the outside of the envelope or envelopes that are made to look like checks). The review and approval of envelopes with additional information other than the four mailing statements must be submitted for a forty-five (45) day review. If no

other statements are added and/or there is no modification of the four mailing statements, then envelopes may be submitted under the File & Use process.

60 - Specific Guidance on Required Documents

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

60.1 - Summary of Benefits (SB)

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111(b)(2), 422.111(f), 423.128(b)(2)

The SB is the stand-alone pre-enrollment document used to inform prospective as well as existing enrollees of the benefits offered by the plan sponsor. The SB is a synopsis document and, therefore, is not intended to include benefit information in the same detail as the Evidence of Coverage. The information within the SB is standardized language to allow beneficiaries to more easily compare the benefits offered by different plan sponsors and includes the following sections:

- *Section (I): The introduction and the beneficiary information section, which informs prospective members of important aspects of enrolling in the plan. This section is standardized language that should not be modified except as indicated in the SB instructions.*

- *Section (II): The benefit comparison matrix, which is an output report of the plan sponsor's PBP, and* Premium Table (for PDPs). PDPs with identical benefits offered in different regions may insert a table indicating the premium in each region. *This section is standardized language that should not be modified except as indicated in the SB instructions.*

- *Section (III): An optional free-form text area, which is limited to six pages. This section can be used by plans to further describe special features of the program.*

- *Section (IV): DE SNPs must provide each prospective enrollee prior to enrollment with a comprehensive written statement that describes:*

    - *The benefits that the individual is entitled to under Title XIX (Medicaid);*

    - *The cost-sharing protections that the individual is entitled to under Title XIX (Medicaid);*

    - *A description of the benefits and cost-sharing protections that are covered under the DE SNP for dual-eligible individuals.*

Plans sponsors are required to include the SB in their enrollment kits and must make the SB available upon request. Therefore, plan sponsors must create and submit an SB for CMS approval. DE SNPs must include the SB in their enrollment kit to fulfill the comprehensive written statement of benefit requirement.

Because the SB is a standardized document, CMS expects that the language for sections I and II will be identical to the SB report in HPMS. Any deviation from this language, outside of an approved hard copy change or global hard copy change, will result in CMS disapproval of the material. Deviations include, but are not limited to, insertion of footnotes, plan specific clarifications, or format alterations, except as indicated in the SB instructions. Plan sponsors should generate their SBs via HPMS.

SNPs should include the required comprehensive written statement in Section IV of the SB when submitting it to CMS for review. SNPs are responsible for ensuring the accuracy of the Medicaid benefits displayed in the SB by communicating with the States and/or utilizing State–specific materials. A template is available on HPMS for plans to use, and technical guidance on the Summary of Benefits can be found in Appendix 1.

If a plan sponsor's bid has been approved, CMS expects that plan sponsors will submit completed SBs to CMS for review. Plan sponsors should not submit SBs with unpopulated brackets for cost-sharing, benefits, etc., after the bid approval.

Plan sponsors offering more than one plan may describe several plans in the same document by displaying the benefits for different plans in separate columns within Section II of the benefit comparison matrix. Since the PBP will only print sections I and II of the SB for one plan, plan sponsors will have to create a side-by-side comparison matrix for two (or more) plans by manually combining the information into a chart format. Plan sponsors will also need to modify Section I of the introduction section to accurately reflect the plans that have been added to Section II of the SB. The side-by-side comparisons are eligible for a ten (10) day marketing review if no other non-global changes are made to the standardized SB.

Section 1876 cost plans must use the standardized SB if they intend to have a plan appear in the Medicare Options Compare and should refer to the SB for 1876 cost plans in Appendix 1. Instructions for use of SB template are provided in § 90.9.

60.2 - Part D ID Card Requirements

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.120(c)

All plan sponsors that offer Part D plans must provide a member identification card to a beneficiary no later than ten (10) calendar days from receipt of CMS confirmation of enrollment, or by the last day of the first month of enrollment, whichever occurs first. Plans should refer to the notification on the weekly or monthly TRR that contains the earliest notification to identify the start of the ten (10) calendar day timeframe. The member identification card must comply

with the most recent version of the National Council for Prescription Drug Program's (NCPDP's) "Pharmacy and/or Combination ID Card" standard. This standard is based on the American National Standards Institute ANSI INCITS 284-1997 standard titled Identification Card – Health Care Identification Cards.

MA-PD *and section 1876 cost* plans *offering a Part D optional supplemental benefit* may merge their medical and Part D ID cards by adding elements that would identify the Part D benefit, or create a separate ID card for the Part D benefit. Either card must comply with the specifications outlined in the most recent version of the NCPDP Pharmacy and/or Combination ID Card Implementation Guide.

In addition to the NCPDP Pharmacy and/or Combination ID Card standard requirements, the front of the Part D ID Card must include the Medicare Prescription Drug Benefit Program Mark (Refer to § 150 for more information.) Plan sponsors must ensure that the identification number on the ID card **cannot** be the SSN or Healthcare Insurance Claim Number (HICN) of the enrolled member.

(Refer to § 30.2 regarding co-branding requirements related to ID cards.)

60.3 - ID Card Information for PPOs and PFFS Plans

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

CMS recommends that all Medicare health plan sponsors, especially PPOs and PFFS plan sponsors, include the phrase *"Medicare limiting charges apply"* on Member ID cards. However, use of this phrase is optional. CMS believes that use of this phrase on a card that most non-contracting providers will see is a reliable method of informing providers of the billing rules for the plan sponsor, and thus could reduce the chance for incorrect or inappropriate balance billing.

CMS also recommends that PPOs and PFFS plan sponsors include a statement that the provider should bill the PPO or PFFS organization and not Original Medicare. CMS believes this statement will help prevent claim processing errors. However, use of this statement is optional.

In order to ensure that a provider has access to a PFFS plan's terms and conditions of payment, CMS also recommends that PFFS plan sponsors include on their member ID cards: (1) the web link to their terms and conditions of payment, and (2) a phone number for providers to call the plan sponsor. If the web link for the terms and conditions of payment is too long to fit on the member ID card, then PFFS plan sponsors are encouraged to appropriately shorten the web link so that it will fit on the member ID card. Inclusion of both of these items on the member ID card is optional.

Refer to § 30.2 information regarding co-branding requirements related to ID cards and § 60.2 for Part D ID requirements.

60.4 - Directories

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111(b)(3)(i), 422.111(e), 423.128(b)(5), 423.128 (c) (1)(E), 422.2260, 423.2260

All plan sponsors are required to create and make available applicable provider *and/or pharmacy* directories for their members and prospective members. Plan sponsors must send a complete directory of providers*/pharmacists* to their members at the time of enrollment and *annually, unless the plan sponsor uses change pages. If using the change pages, plan sponsors must send a complete directory of providers and/or pharmacists to their members at the time of enrollment and at least every three years from the enrollment date or from the date of the last mailing, whichever occurs first.*

Plan sponsors (including section 1876 cost contractors) that have an Internet website must also post copies of their Evidence of Coverage, SB and information on the network of contracted providers and pharmacies (names, addresses, phone numbers, and specialty) on that website.

(**NOTE**: *Employer/Union-only Group Waiver Plans (EGWP) can direct members to their employer for information on the available providers.)*

Change pages constitute either the actual page being changed, or a list of changes with referenced pages. If a plan sponsor chooses to send change pages to members, the following requirements will also apply:

- *Change pages should be issued when there is an update to the directory.*
- *Change pages must be dated.*
- *Change pages should be submitted for forty-five (45) day review*.
- Plan sponsors may choose to disseminate an errata sheet or addendum during the year to update members with respect to changes in providers' or pharmacies' addresses and phone numbers. (Plan sponsors are also required to provide information about contracted providers and pharmacies upon request.)
- *The first time a plan sponsor sends change pages, a cover letter should be included to explain that the plan sponsor will now be sending change pages to members, as opposed to a complete directory. When sending out change pages, the plan sponsor must include a cover letter that explains that the member can receive a complete directory upon request. In addition, the plan sponsor should include information on how to obtain provider/pharmacy network information on the Internet and/or by telephone.*

In instances where significant changes to the provider/pharmacy network occur, the organization must send a special mailing of change pages immediately. The requirement to send a special mailing for significant changes is in addition to all the other mailing timeframes. In

general, the plan sponsor can define "significant changes" when determining whether a special mailing is necessary. However, CMS may also determine if a mailing is needed and may direct the plan sponsor to conduct such a mailing.

60.4.1 - *Pharmacy Directories*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

423.128(b)(5), 423.128 (c) (1)(E)

All Part D plans must include information regarding all contracted network pharmacies in their marketing materials provided at the time of enrollment and annually thereafter, as well as upon beneficiary request *whichever occurs first* (*unless the plan sponsor uses changes pages as described in § 60.4*). Part D sponsors must provide information about the number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs. Part D sponsors may have pharmacy directories for each of the geographic areas they serve (e.g., metropolitan areas, surrounding county areas) provided that all directories together cover the entire service area.

The pharmacy directory must contain the following information as well as any other information located within the CMS model pharmacy directory.

General Disclaimers:

- If a directory is a subset of a service area, Part D sponsors must include the following disclaimer: *"This directory is for <geographic area>." Please contact <Plan Name> at <phone number>, <days and hours of operation>, for additional information."*

- If a plan sponsor lists pharmacies in its network but outside the service area, Part D sponsors must include the following disclaimer: *"We also list pharmacies that are in our network but are outside <geographic area>. Please contact <Plan Name> at <phone number>, <days and hours of operation>, for additional information."*

- Part D sponsors must provide a disclaimer that states the directory is current as of a particular date, that the pharmacy's listing in the directory does not guarantee the pharmacy is still in the network, and where to obtain complete and current information about network pharmacies in the plan's areas.

Preferred *& Other* Network Pharmacies:

- Part D sponsors with preferred and non-preferred pharmacies must describe the features of these pharmacy types in terms of higher or lower cost-sharing and must describe restrictions imposed on members that use non-preferred pharmacies.

- Part D sponsors must indicate which of their pharmacies offer preferred cost-sharing.

Restricted Access to Pharmacies:

- Part D sponsors must indicate when a pharmacy is not available to all members (for example, a community health center pharmacy that is available only to patients of the community health center).

Information about Pharmacies:

- Information required in the pharmacy directory for non-chain pharmacies includes: pharmacy name, address, phone number, and type of pharmacy (e.g., retail, mail order, long-term care, home infusion/I/T/U).

- In lieu of providing the addresses for all locations, sponsors may provide a toll-free customer service number for chain pharmacies and a TTY number that an enrollee can call to get the locations and phone numbers of the chain pharmacies nearest to their home. If a chain pharmacy does not have a toll-free number, plan sponsors should include a central number for the pharmacy chain. If the chain pharmacy does not have a central number for enrollees to call, then plans must list each plan's chain pharmacy and phone number in the directory. If the chain pharmacy does not have a TTY number, plan sponsors are instructed to list the TRS Relay number 711. Plan sponsors should not list their own customer service number as a pharmacy phone number or TTY number.

- Part D sponsors may indicate which of their network pharmacies support e-prescribing in their pharmacy directories.

- Part D sponsors must indicate which of their retail pharmacies provides an extended day supply of medications.

If a plan sponsor chooses to use the CMS model pharmacy directory and the disclaimers are not contained within the model, inserting the disclaimers will still make the material eligible for a ten (10) day review. (If Part D sponsors use a search engine on their websites in lieu of posting the pharmacy directory, the search engine must include all of the information listed above.)

60.4.2 - *Provider Directories*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111(b)(3)(i), 422.111(e)

MA, MA-PD, and section 1876 cost plans provider directories must contain all information within the CMS model provider directory. Note that for DE SNPs, the Medicaid indicator in the provider directory is a required element for those plans that have a contract with the State

Medicaid Agency. A provider directory that includes the Medicaid indicator will still qualify for a ten (10) day review. Plan sponsors are required to disclose all of the plan sponsor's contracted providers to each enrollee in *a* clear, accurate, and standardized form prior to the effective date of enrollment or within ten (10) calendar days of receipt of the enrollment confirmation and at least annually thereafter (with the exception of those plans *that* utilize "change pages" as outlined in § 60.4. *The directory is provided to new members upon enrollment and current members on an annual basis unless the plan sponsor uses change pages as outlined in § 60.4. MA, MA-PD and section 1876 cost plan sponsors that do not combine the model provider/pharmacy directories must list all Part B and Part D eligible contracted pharmacies in the provider directory.*

Plan sponsors may indicate which of their participating physicians or physician practices support e-prescribing. Model directories that include e-prescribing information will still be considered a model document eligible for a ten (10) day review.

60.4.3 - *Primary Care Provider (PCP) and Specialty Directories*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

422.111(b)(3)(i), 422.111(e), 423.128(b)(5), 423.128 (c)(1)(E)

Plan sponsors may print a separate directory for each sub-network and disseminate this information to members in that particular sub-network. This practice is permissible provided that the directory clearly states that the lists of providers for other networks is available and will be provided to members upon request.

Plan sponsors may publish separate PCP and specialty directories on the condition that both directories are given to enrollees prior to the effective date of enrollment or within ten (10) calendar days of receipt of the enrollment *confirmation* and at least annually thereafter. Plan sponsors that use sub-networks of providers must clearly delineate these sub-networks (preferably by listing the providers as a separate sub-network) and describe any restrictions imposed on members that use these sub-networks. This is particularly important since beneficiaries could choose their primary care physician without realizing that this choice restricts them to a specified group of specialists, ancillary providers, and hospitals. Plan sponsors must also clearly describe the process for obtaining services in these networks and sub-networks, including any referral requirements, as well as any out-of-network coverage or point-of-service option.

60.4.4 - *Combined Provider/Pharmacy Directory*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111(b)(3)(i), 423.128(b)(5)

MA-PD *plans and section 1876 cost* plans *that offer prescription drug coverage* may combine the model *provider* and model pharmacy directories in one document. If the plan sponsor chooses to use the two model directories *without modification* and combine them into one document, *the materials can be submitted either File & Use or for a ten (10) day review period per the rules articulated below:*

- *Model provider and pharmacy directories used separately and without modification can be submitted File & Use.*
- *Model provider and pharmacy directories combined without any modification can be submitted File & Use.*
- *Model provider and pharmacy directories combined with the pharmacy section removed from the provider directory can be submitted for ten (10) day review.*
- *Model provider and pharmacy directories used separately or combined, and otherwise modified, must be submitted for forty-five (45) day review*.

60.4.5 - *Mailing the Provider/Pharmacy Directory to Addresses with Multiple Members*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42CFR 422.111(b)(3)(i), 423.128(b)(5)

With respect to the mailing of the directory at the time of enrollment and annual thereafter, plan sponsors have the option to either mail one directory to every member, or to mail one directory to every address where up to four members reside. (Individuals in, for example, apartment buildings, are only considered to be at the "same address" if the apartment number is the same.) Please note that every member must still receive his or her own directory at the time of enrollment *and annually thereafter.*

If a plan sponsor chooses to mail the directory to every address where up to four members reside, the following requirements apply:

- If a member at that address subsequently requests that the plan sponsor mail another copy of the directory, the plan sponsor must mail him/her a directory.

- *When mailing a directory to one address, the plan sponsor must include the name of at least one of those individuals in the mailing address. To avoid confusion, the plan sponsor is encouraged to include the names of all individuals.*

If a member has previously elected to receive a provider directory electronically, the plan sponsor may fulfill the requirement of mailing an annual directory through e-mail. Note that if the e-mail sent to members contains a link to the plan sponsor's website (as opposed to an attachment with the directory), the e-mail must clearly direct the member to the location of the directory on the plan sponsors website.

60.4.6 - Changes to Provider Network

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111(e)

All MA and MA-PD plan sponsors must make a good faith effort to provide written notice of termination of a contracted provider at least thirty (30) calendar days before the termination effective date to all members who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all members who are patients of that primary care professional must be notified.

60.5 - Formulary and Formulary Change Notice Requirements

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.120(b)(5) 423.128 (a)-(e)

Part D sponsors must provide a list of drugs included on their Part D formulary to enrollees at the time of enrollment and at least annually thereafter. Because CMS regulations do not specify whether this list should be an abridged or comprehensive list of covered drugs, and given concerns that a comprehensive formulary would be costly for plan sponsors to print and distribute and confusing for enrollees to use, CMS allows plan sponsors to provide an abridged version of their formulary provided certain requirements, described below, are met.

Part D sponsors are responsible for ensuring that their marketed formularies (both those in print and those available on their websites) are consistent with their HPMS approved formulary file. In addition to each covered drug displaying at the correct cost-sharing tier and with the approved utilization management edits *(i.e., prior authorization, step therapy or quantity limits),* the formulary drug category and class must also be consistent between the HPMS approved formulary file and the print and web-based marketing versions. Part D plan sponsors must include the applicable HPMS approved formulary file submission ID and version number on their marketed (print and web-based) formularies. This HPMS approved formulary file number refers to the HPMS formulary submission ID number of the approved formulary that is being marketed. The formulary submission version is also required. In the event that a discrepancy is identified, the plan sponsor must continue to cover the drug(s) at the more favorable cost share or with less restrictive utilization management for the beneficiary through the end of the contract year.

Any drug adjudicated as a formulary drug at the point of sale must be included in Part D sponsor marketing materials. This applies to drugs that exist on the approved HPMS formulary as well as drugs covered as Part D formulary enhancements to the approved formulary. Generally these drugs are expected to relate to newly approved brand or generic drugs (including new formulations and strengths) that do not currently reside on the Formulary Reference File (FRF),

but that would likely be added during subsequent FRF updates. These marketed formulary drug enhancements must be added to the HPMS formulary once the drugs are represented on the FRF.

60.5.1 - Abridged Formulary

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.128

At a minimum, a Part D sponsor's printed abridged formulary document must include the following information:

- Plan Name on cover page
- "<Year> Formulary (List of Covered Drugs)" on cover page
- "PLEASE READ: THIS DOCUMENT CONTAINS INFORMATION ABOUT THE DRUGS WE COVER IN THIS PLAN" on cover page
- The following statement: "Note to existing members: This formulary has changed since last year. Please review this document to make sure that it still contains the drugs you take."
- The following disclaimer: "This document includes <Plan's Name> partial formulary as of <formulary date>. For a complete, updated formulary, please visit our <website address> or call <toll free number>, <days and hours of operation>. TTY users should call <toll free TTY number>."
- The definition of a formulary as compared to an abridged formulary (42 CFR 423.4 defines "formulary" as "the entire list of Part D drugs covered by a Part D plan").
- An explanation of how to use the Part D plan's formulary document.
- The following statement: "<Part D Plan Name> covers both brand name drugs and generic drugs. A generic drug is approved by the FDA as having the same active ingredient as the brand name drug. Generally, generic drugs cost less than brand name drugs.
- A statement describing the Part D plan's general utilization management procedures, as well as a statement that the formulary may change during the year (**NOTE**: As provided under 423.120(b)(6), a Part D plan **may not** make negative formulary changes to its formulary from the beginning of the annual coordinated election period through sixty (60) days after the beginning of the contract year.)
- The document must also include the date the formulary was last updated and describe how to obtain updated formulary information.

- An explanation of how to obtain an exception to the Part D plan's formulary, utilization management tools or tiered cost sharing and a description of the plan's drug transition policy.

- Plan contact information for additional information or questions on the formulary.

- A chart (the approved CMS formulary) of covered drugs organized by therapeutic category that includes at least two covered drugs for each therapeutic class. Exceptions to this include when only one drug exists in the category or class or in the case where two drugs exist in the category or class, and one is clinically superior to the other. The category or class names must be the same as those found on the CMS approved Part D plan formulary. **(NOTE**: While Part D plans must ensure that at least two drugs per therapeutic class are included within the abridged formulary, Part D plans have the option to include the therapeutic classes as subheadings within the abridged formulary, as this level of detail may be confusing for beneficiaries.) The row of the chart must include at least the three items described below.

    - Drug Name: We suggest capitalizing brand name drugs (e.g., LIPITOR) and listing generic drugs in lowercase italics (e.g., penicillin). Part D plans may include the generic name of a drug next to the brand name of the drug. The abridged formulary may only consist of drugs included on the CMS approved HPMS formulary. Formulary drug enhancements described in § 60.5 **may not** be included in the abridged formulary document.

    - Tier Placement: Part D plans that provide different levels of coverage for drugs depending on their tier should include a column indicating the drug's tier placement and the corresponding tier label description (e.g. Generic or Preferred Brand) from the approved PBP. Part D plans may also choose to include a column providing the co-payment or co-insurance amount for each tier.

    - Utilization Management (UM): Part D plans must indicate any applicable UM tools (e.g., prior authorization, step therapy, and quantity limit restrictions) for the drug. A description of the indicator used to describe the UM tools must be provided somewhere within the document (e.g., in footnotes). For example, a Part D plan may choose to designate a prior authorization on a drug by placing an asterisk next to the name of the drug.

- Because many beneficiaries may only know the name of their prescription and not its therapeutic class, the abridged formulary must also include an index listing drugs in alphabetical order that directs the reader to the page containing complete information for that drug (e.g., name, tier placement, and utilization management strategy).

- Plan sponsors must explain any symbols or abbreviations used to indicate utilization management restrictions, drugs that are available via mail-order,

excluded drugs, free first fill drugs, limited access drugs, drugs covered in the coverage gap, and drugs covered under the medical benefit (for home infusion drugs only).

60.5.2 - *Comprehensive Formulary*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.4, 423.128(c)(1)(v)

As provided in 42 CFR 423.128(c) (1) (v), a Part D plan upon the request of a Part D eligible individual, must provide "the Part D plan's formulary." 42 CFR 423.4 defines "formulary" as "the entire list of Part D drugs covered by a Part D plan." These provisions together require a Part D plan sponsor to provide a comprehensive written formulary to any potential or current enrollee upon his or her request.

NOTE: If an individual contacts the Part D plan to request a comprehensive formulary, the Part D plan may offer to provide the individual with coverage information for specific drugs. That is, a customer service representative may offer to look up the individual's prescription(s) in order to provide information about coverage, tier placement, and utilization management procedures for his or her drugs. Customer service representatives also may inform individuals that current and comprehensive formulary information is available on the Part D plan's website. Nevertheless, the Part D plan still must provide the requested comprehensive written formulary unless the individual indicates otherwise.

The comprehensive formulary must include the same information provided within the abridged formulary document, except that the comprehensive formulary must include the entire list of drugs covered by the Part D plan and excludes the disclaimer informing beneficiaries that they can obtain a comprehensive formulary by contacting the Part D plan. Drugs adjudicated at the point of sale as formulary drugs *that are not found on the CMS approved HPMS formulary* must be included in the comprehensive formulary. This may include drugs that are not found on the CMS approved HPMS formulary as described in § 60.5.

60.5.3 - *Changes to Printed Formularies*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.128(a)-(c)

Beneficiaries have a legitimate expectation that they will have access to the Part D drugs included in marketed formularies. While Part D sponsors can readily update their online formularies, the same is not true for printed formularies provided to plan enrollees.

Given the "bait and switch" nature of mid-year non-maintenance formulary changes (defined in § 30.3.3.3 of Chapter 6 of the Prescription Drug Benefit Manual), beginning in contract year 2010, Part D sponsors will be expected to update all impacted abridged and comprehensive printed formularies with any CMS approved non-maintenance formulary changes.

Part D sponsors may make any necessary formulary changes via errata sheets mailed to affected members. While Part D sponsors retain the flexibility to utilize other processes for notifying beneficiaries of non-maintenance changes to their printed formularies, CMS expects Part D sponsors to send out errata sheets with formulary changes no less than monthly to the extent that any negative formulary changes have occurred and that affected members will receive a hard copy of such changes (website updates alone will not suffice). This new requirement does not extend to mid-year maintenance changes defined in § 30.3.3.2 of Chapter 6 of the Prescription Drug Benefit Manual. Changes to previously printed formularies resulting from mid-year maintenance changes may be made at the time of the next printing. This is not a substitute for the required advance 60 days notice to affected beneficiaries.

60.5.4 - *Formularies Provided on Plan Websites*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.128(d)(2)(ii)

In addition to the preceding print formulary requirements, plan sponsors must include their current formulary and any applicable quantity limit restrictions, prior authorization criteria and step therapy criteria on their website. To meet this requirement Part D plan sponsors must provide an electronic copy of the comprehensive formulary, prior authorization and step therapy documents that individuals may view and/or print. The formulary should include the tier level and tier label description as well as the quantity limit amount and quantity limit days supply. *Unlike for the printed abridged and comprehensive formularies, it is not acceptable to merely indicate that UM applies to a drug for the downloadable formulary documents.* The UM documents must include all prior authorization and step therapy criteria applied to each formulary drug. While Part D sponsors may make minor modifications on plan websites with regard to the HPMS prior authorization and step therapy criteria to address issues such as abbreviations and/or grammatical truncation, Part D sponsors will be expected to display all of the information contained within the HPMS files. For drugs with a Part B versus D administrative prior authorization requirement, the following statement must be included: *"This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination."* The information in the comprehensive formulary and UM documents must:

- Be available at the start of each new contract year enrollment period.
- Be updated at least once per month and must be accessible by a drug name search.

- Include the date when the formulary and utilization management documents were last updated *to include "Updated MM/YYYY" or "No changes made since MM/YYYY".*

- Be posted as PDF files that allow for printing, content copying for accessibility, page extraction, and document assembly. In addition to the PDFs, Part D plans may also post the comprehensive formulary in other downloadable formats.

CMS suggests that Part D plan sponsors also provide a search tool that allows individuals to search for their specific prescription drug. The search tool **may not** be used as a substitute for the downloadable comprehensive formulary, prior authorization and step therapy criteria documents (PDFs). However, if a search tool is made available, it must be available for all formulary drugs. In addition, CMS also expects the search tool to include the following elements:

- Definition of formulary. Part D plan sponsors may either include this information or provide a link to this information in an introductory screen.

- An explanation of how to use the search tool.

- The following statement: *"<Part D Plan Name> covers both brand name drugs and generic drugs. Generic drugs have the same active-ingredient formula as a brand name drug. Generic drugs usually cost less than brand name drugs and are rated by the Food and Drug Administration (FDA) to be as safe and effective as brand name drugs."*

- A statement that the formulary may change during the year.

- Search results that indicate whether a drug is covered, its tier placement (including the tier number and tier label description), and any applicable utilization management requirements. If quantity limit restrictions apply, the quantity limit amount and days' supply must be displayed. If prior authorization or step therapy restrictions are applicable, then the criteria must also be included. For drugs with a Part B versus D administrative prior authorization requirement, the following statement must be included: *"This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination."*

- An explanation of how to obtain an exception to the Part D plan's formulary, utilization management tools or tiered cost sharing. This information or a link to this information must be included in both an introductory screen and when search results indicate a drug is not covered.

- An indicator to identify mail-order availability, excluded drugs, free first fill drugs, limited access drugs, drugs covered in the coverage gap, and drugs covered under the medical benefit (for home infusion drugs only).

- Include the date when the search tool information was last updated.

In addition to the information above, a plan may also choose to include search results that list formulary alternatives for the drug entered in the online search tool. The Part D plan may choose to include non-formulary alternatives in addition to the formulary alternatives; however, the formulary alternatives must be clearly marked as formulary drugs without the need for further navigation. If not all formulary alternatives will be listed, the plan must include the following disclaimer: "*This is not a complete list of all formulary alternatives covered by the Part D plan for the drug you have selected.*"

Formulary information available on a website is subject to review by CMS. Review of these materials will follow the procedures for review of websites, which is described in § 100.

60.5.5 - Other Formulary Documents

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.128(b)(4)

Part D plans may develop additional formulary documents provided that the comprehensive and abridged formulary documents are developed and distributed in compliance with § 60.5. For example, Part D plans may choose to develop a formulary that lists all of their preferred drugs or is tailored to individuals with specific chronic conditions, as long as these items supplement the two required documents rather than replace them.

The following disclaimer must also be displayed prominently on the cover of the document: *"This is not a complete list of drugs covered by the Part D plan. For a complete listing, please call <Customer Service Phone Number> or log onto <website address>."*

60.5.6 - Provision of Notice to Beneficiaries Regarding Formulary Changes

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.120(b)(5)

Part D plans must provide at least sixty (60) days notice to beneficiaries before removing a Part D drug from the Part D plan's formulary; adding prior authorization, quantity limits, step therapy or other restrictions on a drug; or moving a drug to a higher cost-sharing tier. Part D plans can determine the most effective means by which to communicate formulary change information to these parties, including electronic means. Part D sponsors should refer to § 30.3.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual regarding the notice requirements.

60.5.7 - Provision of Notice to Other Payers Regarding Formulary Changes

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.120(b)(5)

Prior to removing a covered Part D drug from its formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D sponsor must provide at least sixty (60) days notice to CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies and pharmacists prior to the date such change becomes effective. Part D sponsors should refer to § 30.3.4.2 of Chapter 6 of the Medicare Prescription Drug Benefit Manual for additional information on this notice requirement.

60.6 - Part D Explanation of Benefits

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.128(e)

Part D plan sponsors must send an Explanation of Benefits (EOB) to plan enrollees during months in which enrollees utilize their prescription drug benefits. Part D sponsors must ensure that enrollees who utilize their prescription drug benefits in a given month receive their EOB by the end of the month following the month in which they utilized their prescription drug benefits.

The EOB must include the following information:

- The drugs for which payment was made and the total amount of payment for those drugs, including true out of pocket (TrOOP)-eligible amounts.
- A notice of the enrollee's right to request an itemized statement. *The EOB should contain sufficient information necessary for the beneficiary to understand their prescription drug coverage and benefits. However, to the extent a beneficiary requests additional items not already addressed in the EOB, a plan must provide this information.*
- A notice of the enrollee's appeal and grievance rights, including the exceptions process.
- Include the cumulative, year-to-date total amounts of benefits (total drug spend) provided relative to:
    - The deductible, if applicable.
    - The initial coverage limit for the current year, if applicable.
    - The annual out-of-pocket-threshold.

- This cumulative total must include adjustments made as a result of retroactive adjustments (for example, those based on information received from other plans, reversed claims, and supplemental payer adjustments).

- The cumulative, year-to-date total of TrOOP costs. This cumulative total must include adjustments made as a result of adjustments made (for example, those based on information received from other plans, reversed claims, and supplemental payer adjustments). If adjustments have been made after the end of the plan year that results in no change to the enrollee's liability, the plan does not need to send another EOB.

- Notice regarding formulary changes to affected enrollees, as provided in 42 CFR 423.120(b)(5) and in § 60.5.

NOTE: Plan sponsors are encouraged to include language promoting the LIS program on the EOB.

60.7 - Annual Notice Of Change (ANOC) and Evidence of Coverage (EOC)

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111(a)(3), 422.111(d)(2), 423.128 (a)(3)

With the exception of fully integrated DE SNPs, section 1876 cost plans not offering Part D and employer/union group plans, plan sponsors must ensure their current members receive the ANOC and EOC no later than October 31st of each year. New Enrollees with an effective date of November 1st or December 1st should receive both an EOC for the current contract year and an ANOC/EOC for the upcoming contract year. Additionally, plan sponsors must send new enrollees with an effective date of January 1st or later a standalone EOC for that contract year.

In the instances listed above where plan sponsors are sending the standalone EOC, the document may be edited to remove all references to the ANOC. In addition, plan sponsors doing so do not need to resubmit the standalone EOC under a new code provided they have previously submitted a combined ANOC/EOC in HPMS.

Regardless of the effective date, the document must be provided to all new enrollees no later than ten (10) calendar days from receipt of CMS confirmation of enrollment or by the last day of the first month of enrollment, whichever occurs first. Plan sponsors should refer to the notification on the weekly or monthly TRR that contains the earliest notification to identify the start of the ten (10) calendar day timeframe.

DE SNPs may separate the ANOC from the EOC, but must send the ANOC to current members by October 31st and send the EOC to enrollees by December 31st. Beneficiaries of employer/union group plans must receive their ANOC and EOCs no later than fifteen (15) days before the beginning of the Annual Coordinated Election Period (ACEP) which is based on the

employer/union sponsor's open enrollment period (refer to § 20.3.2.1.2 of Chapter 9 of the Medicare Managed Care Manual and § 20.3.2.1.2 of Chapter 12 of the Prescription Drug Benefit Manual).

Section 1876 cost plans offering Part D benefits must send the combined standardized ANOC/EOC to their enrollees by October 31 of each year. Section 1876 cost plans that do not offer Part D benefits must send the combined ANOC/EOC by December 1 of each year.

To ensure that plan sponsors are mailing their ANOC/EOC timely, plan sponsors must indicate the actual mail date in HPMS within three (3) days of mailing. Plan sponsors that mail in waves should enter the actual date of the last wave. For instructions on meeting this requirement, refer to the update material section of the Marketing Module- User Guides in HPMS.

60.8 - Mid-Year Changes Requiring Enrollee Notification

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111(d)(3)

Mid-year benefit enhancements are no longer permitted. However, if a national coverage determination takes effect mid-year, and is covered under the contract, or is covered on a fee-for-service basis outside the contract, but the plan sponsor chooses to offer coverage to beneficiaries, such services may be added mid-year. In such cases, the plan sponsor must notify enrollees of this change at least thirty (30) days before the effective date of the change. If the newly covered service is covered outside the contract, the enrollee must be told that he or she could receive this service from any Medicare provider. In the case of a change to plan rules during a contract year (note that these rule changes must be positive for enrollees relative to the rules articulated in the plan sponsor's post enrollment materials, the plan sponsor must notify CMS and obtain its approval and must also notify enrollees at least thirty (30) days before the effective date of the change. The plan sponsor may use a variety of mechanisms to inform enrollees of the mid-year change, including one-time mailings, newsletters and other vehicles.

70 - *Rewards and Incentives, Promotional Activities, Events, and Outreach*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

70.1 - General Guidance about Promotional Activities

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Promotional activities (including provider promotional activities) must comply with all relevant Federal and State laws. Plan sponsors may be subject to compliance and/or enforcement actions if they offer or give something of value to a Medicare beneficiary that the plan sponsor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare. Marketing representatives must clearly identify the types of products that will be discussed before marketing to a potential enrollee. This includes all sales presentations, events, appointments, and outbound calls that are permissible under CMS' unsolicited contacts guidance. Additionally, plan sponsors are prohibited from offering rebates or other cash inducements of any sort to beneficiaries.

Furthermore, plan sponsors are prohibited from offering or giving remuneration to induce the referral of a Medicare beneficiary, or to induce a person to purchase, or arrange for, or recommend the purchase or ordering of an item or service paid in whole or in part by the Medicare program.

Any promotional activities or items offered *by plan sponsors, including those that will be used to encourage retention of members:*

- *Must be of nominal value (refer to § 70.2 for additional information on nominal value);*
- Must be offered to all *people* eligible *to enroll* without discrimination;
- **Must not** be offered in the form of cash or other monetary rebates;
- **May not** be items that are considered a health benefit (e.g., a free checkup);
- ***May not*** *consist of lowering or waiving co-pays should the person enroll;*
- ***May not*** *be items that are otherwise available, to the general public, for free;*
- ***May not*** *be used in pre-enrollment advertising, marketing, or promotion of the plan, such as in the PBP, SB, ANOC or EOC;*
- ***May not*** *be structured to steer enrollees to particular providers, practitioners, or suppliers;*
- *May be discussed in direct mailings to enrollees (as long as there is no violation of the HIPAA Privacy laws);*
- *Must be tracked and documented during the contract year;*
- *Are subject to grievances by the enrollee (consequently, the plan must explicitly advise enrollees of the right to grieve and the process for filing a grievance);and*
- ***May not*** *be tied directly or indirectly to the provision of any other covered item or service.*

70.1.2 - General Guidance about Rewards and Incentives

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Rewards and incentives may only be offered to promote one of the following target activities:

- Welcome to Medicare" visit (includes a referral for an ultrasound screening for abdominal aortic aneurysm for eligible beneficiaries)
- Adult Immunization – influenza, pneumococcal and Hepatitis B vaccination
- Colorectal Cancer Screening
- Screening Mammography
- Screening Pap Test and Pelvic Examination
- Prostate Cancer Screening
- Cardiovascular Disease Screening
- Diabetes Screening
- Glaucoma Screening
- Bone Mass Measurement
- Diabetes Self-Management, Supplies and Services
- Medical Nutrition Therapy
- Smoking Cessation
- *HIV screening for high risk groups*

The reward items given to plan enrollees for doing any of the above target activities are subject to the following requirements:

- *Each reward item must have a retail value monetary cap not to exceed $10 per item or $50 in the aggregate on an annual basis per member per year;*
- *Must be offered to all eligible members without discrimination;*
- ***Must not** be offered in the form of cash or other monetary rebates;*

- ***May not** be items that are considered a health benefit (e.g., a free checkup);*
- **May not** consist of lowering or waiving co-pays;
- **May not** be items that are otherwise available, to the general public, for free;
- **May not** be used in pre-enrollment advertising, marketing, or promotion of the plan, such as in the PBP, SB, ANOC or EOC (rewards and incentives may only be discussed in post-enrollment notifications);
- **May not** be structured to steer enrollees to particular providers, practitioners, or suppliers;
- May be discussed in direct mailings to enrollees (as long as there is no violation of the HIPAA Privacy laws);
- Must be tracked and documented during the contract year;
- Are subject to grievances by the enrollee (consequently, the plan must explicitly advise enrollees of the right to grieve and the process for filing a grievance);
- **May not** be tied directly or indirectly to the provision of any other covered item or service; and
- *Are subject to disclosure requirements – that is, the plan must clearly inform the enrollee what target activities are rewarded, what limitations, if any, apply, and how to claim the reward items; and*
- *Must comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries.*

70.2 - Nominal Gifts

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268(b), 423.2268(b)

Pursuant to 42 CFR 422.2268(b) and 42 CFR 423.2268(b), plan sponsors can offer *promotional gifts to* potential enrollees at all marketing activities as long as such gifts are of nominal value and are provided whether or not the individual enrolls in the plan. Nominal value is currently defined as an item worth $15 or less, based on the retail *value* of the item. The following rules must be followed when providing gifts of a nominal value:

- If more than one item is offered by a plan sponsor at any marketing activities (for example a pen and a flashlight), the combined value of all items offered to a participant **must not** exceed the nominal value we stipulate.

- If a nominal gift provided is one large gift that is enjoyed by all in attendance (for example a concert or a magician) the total retail cost must be $15 or less when it is divided by the estimated attendance. For planning purposes, anticipated attendance may be used, but must be based on venue size, response rate, or advertisement circulation.

- Cash gifts are prohibited, including charitable contributions made on behalf of potential enrollees and including gift certificates and gift cards that can be readily converted to cash, regardless of dollar amount.

  NOTE: Gift cards must be used in their entirety and the balance **cannot** be issued in cash. Plan sponsors should refer to the Office of Inspector General's website regarding advisory opinions on gift cards at http://www.oig.hhs.gov/fraud/advisoryopinions.asp.

The dollar amount associated with the definition will be periodically reassessed by CMS. A plan sponsor may offer a prize of over $15 to the general public (for example, a $1,000 sweepstakes) as long as the prize is offered to the general public and not just to Medicare beneficiaries, is not routinely or frequently awarded and is awarded without regard to whether the individual enrolls in a plan.

70.2.1 - Exclusion of Meals as a Nominal Gift

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268(p), 423.2268(p)

Plan sponsors **may not** provide prospective enrollees with meals, or have meals subsidized, at any event or meeting at which plan benefits are being discussed and/or plan materials are being distributed (for example a hotel conference room, restaurants, soup kitchen, shelter, or senior center).

Plan sponsors are, however, allowed to provide refreshments and light snacks to prospective enrollees. Plan sponsors must use their best judgment on the appropriateness of food products provided, and must ensure that items provided could not be reasonably considered a meal, and/or that multiple items are not being "bundled" and provided as if a meal.

Meals may be provided at educational events provided the event meets CMS' strict definition of an educational event, and complies with the nominal gift requirement in § 70.2. *Meals are not allowed at sales/marketing events. Refer to § 70.7 for guidance regarding education events.*

While CMS does not intend to define the term "meal" or create a comprehensive list of food products that qualify as light snacks, items similar to the following could generally be considered acceptable:

- Fruit
- Raw vegetables

- Pastries
- Cookies or other small bite size dessert items
- Crackers
- Muffins
- Cheese
- Chips
- Yogurt
- Nuts

It is the responsibility of plan sponsors to monitor the actions of all agents selling their plan(s) and take proactive steps to enforce this prohibition. Oversight activities conducted by CMS will verify that plan sponsors and agents are complying with this provision, and enforcement actions will be taken against the plan sponsor as necessary.

70.2.2 - Nominal Gift Disclaimer

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Plan sponsors must include a written statement on all materials advertising/promoting drawings, prizes or any promise of a free gift that there is no obligation to enroll in the plan. For example:

- "Eligible for a free drawing and prizes with no obligation."
- "Free drawing without obligation."

70.3 - Unsolicited E-mail Policy

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268(d) 423.2268(d)

A plan sponsor **may not** send e-mails to a beneficiary, unless the Medicare beneficiary agrees to receive e-mails from the plan sponsor and the beneficiary has provided his/her e-mail address to the plan sponsor. Furthermore:

- Plan sponsors are prohibited from renting and purchasing e-mail lists to distribute information about MA, *PDP*, or *section 1876 cost plans*.
- *Plan sponsors may not e-mail prospective members at e-mail addresses obtained through friends or referrals*
- *Plan sponsors must provide an opt-out process for beneficiaries who no longer wish to receive e-mail communica*tions.

70.4 - Marketing through Unsolicited Contacts

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268(d), 423.2268(d)

As reflected in 42 CFR 422.2268(d) and 42 CFR 423.2268(d), there is a general prohibition on marketing through unsolicited contacts. In general this prohibition includes the following and may extend to other instances of unsolicited contact that may occur outside of advertised sales or educational events. Some examples include:

- *Door to door solicitation including leaving information such as a leaflet, flyer, or door hanger, or leaving information such as a leaflet or flyer on someone's car.*
- Approaching beneficiaries in common areas (e.g., parking lots, hallways, lobbies, etc.)
- *Telephonic or electronic solicitation including leaving electronic voicemail messages on answering machines, text message, or e-mail contact.*
- *NOTE: Agents/brokers who have a pre-scheduled appointment which becomes a "no-show" may leave information at the no-show beneficiary's residence.*

The prohibition on marketing through unsolicited contacts does not extend to mail and other print media provided they are constructed and approved in accordance with the information set forth in these *Medicare Marketing* Guidelines. Leads may still be generated through mailings, websites, advertising and public sales events. Refer to § 70.3 regarding email policy.

Plan sponsors will be held accountable for all actions of agents/brokers selling their products, and plans/agents/brokers should be wary of any company selling beneficiary contacts that claims to be permissible under our guidance. Plan sponsors should also note that *Medicare Marketing* Guidelines and regulations apply to Medicare age-ins as well as existing beneficiaries.

In addition, permission given by a beneficiary to be called or otherwise contacted is to be considered short-term, event-specific, and **may not** be treated as open-ended permission for future contacts. All business reply cards used for documenting beneficiary agreement for a contact must be submitted to CMS for review/approval.

70.5 - Specific Guidance on Telephonic Contact

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268(d), 423.2268(d)

Because telephonic contact with Medicare beneficiaries is performed for a variety of reasons, the following guidance has been developed to further clarify the scope of the restrictions. While CMS understands that plan sponsors might have previously received beneficiary consent to contact them for sales activities, we view that previous consent as limited in scope, short-term, *and* event-specific. *Consent* **may not** be treated as open-ended permission for future contacts. The exceptions are for agents contacting their own clients and also plans and their employed or contracted agents contacting their current members. *In addition, all plans sponsors must be in compliance with § 170 regarding the use of beneficiary data as related to telephonic contact. Also refer to § 80.1.9 for information about script review and approval.*

Prohibited telephonic activities include, but are not limited to, the following:

- Conducting or allowing unsolicited contacts, including unsolicited outbound calls, to beneficiaries to offer a non-MA or non-PDP product if the unsolicited contact also discusses MA or PDP products. (Examples of non-MA or non-PDP products include, but are not limited to: a discount prescription drug card, a Medigap plan, a needs assessment, an educational event, a review of Medicare coverage options, or any other service or product that is not an MA plan or PDP.)

- Referrals of beneficiaries and/or their contact information resulting in an unsolicited contact. The purpose of this policy is to avoid unsolicited contacts based on a claim by an agent/broker that they have a "referral" from a friend or other third-party. Plan sponsors or agents/brokers are permitted to leave contact information such as business cards with beneficiaries for them to give to friends that they are referring to the agent or plan sponsor. However, in all cases, a referred beneficiary needs to contact the plan or agent/broker directly. A call from an agent to a beneficiary who was referred would be considered an unsolicited contact.

- Outbound marketing calls, unless the beneficiary requested the call. This includes contacting existing members to market other Medicare products, except as permitted below.

- Calls to former members who have disenrolled, or to current members who are in the process of voluntarily disenrolling, to market plans or products, except as permitted below. Members who are voluntarily disenrolling from a plan should not be contacted for sales purposes or be asked to consent in any format to further sales contacts.

- Calls or visits to beneficiaries who attended a sales event, unless the beneficiary gave express permission at the event for a follow-up call or visit (including a completed scope of appointment form).

- *Calls to beneficiaries to confirm receipt of mailed information, except as permitted below.*

Plan sponsors may do the following:

- Contact beneficiaries who submit enrollment applications to conduct quality control and agent/broker oversight activities. Scripts for this purpose, like all other call scripts, must be submitted to CMS for review and approval.

- Contact their members or use third parties to contact their current members. Examples of allowed contacts include, but are not limited to, calls to members aging-in to Medicare from commercial products offered by the same sponsoring organization and calls to an organization's existing Medicaid plan members to talk about its Medicare products. *However, plan sponsors may not conduct unsolicited calls to their Medigap enrollees regarding their, MA, Part D or section 1876 cost plan products.*

- Conduct outbound calls to existing members to conduct normal business related to enrollment in the plan, including calls to members who have been involuntarily disenrolled to resolve eligibility issues.

- Call former members after the disenrollment effective date to conduct disenrollment surveys for quality improvement purposes. Disenrollment surveys may be done by phone or sent by mail, but neither calls nor mailings may include sales or marketing information.

- Under limited circumstances and subject to advance approval from the appropriate CMS Regional Office, call LIS-eligible members that a plan is prospectively losing due to reassignment to encourage them to remain enrolled in their current plan.

- *Call beneficiaries who have expressly given permission for a plan or sales agent to contact them, for example by filling out a business reply card or asking a customer service representative (CSR) to have an agent contact them. This permission applies only to the entity from which the beneficiary requested contact, for the duration of that transaction, for the scope of product (e.g., MA-PD plan or PDP) previously discussed or indicated in the reply card.*

- *Return beneficiary phone calls or messages, as these are not unsolicited.*

- *Contact current enrolled members via an automated telephone notification to inform them about general information such as the AEP dates, availability of flu shots, upcoming plan changes and other important information.*

Agents/Brokers:

- May contact members that they enrolled in a plan to discuss plan issues and market other plan options, but **cannot** conduct unsolicited phone calls to other beneficiaries or plan members. During an agent's outbound call to a client, the agent is not required to set up an appointment to discuss other available plans/products with the beneficiary.

- May initiate a phone call to confirm an appointment that has already been agreed to by a beneficiary via a completed scope of appointment form.

Plan sponsors **may not** accept an MA plan or PDP appointment that resulted from an unsolicited contact with a beneficiary (including if the call started based on a non-MA or non-PDP product). We reiterate that any agent/broker who is a producer for an MA or PDP contractor is subject to the CMS marketing requirements at any point that an MA or PDP product becomes part of a discussion with a beneficiary, even if during a sale of an unrelated product, such as long-term care insurance. (See scope of appointment guidance in § 70.9.1)

If during the course of an outbound call by a Medigap issuer the beneficiary requests additional information on a MA or PDP product, at this time a discussion can be held on the MA or PDP product, as long as the call is being recorded.

Furthermore, third-parties **may not** make unsolicited MA or PDP marketing calls to beneficiaries (other than to current plan members if contracted by a plan, as described below) to set up appointments with potential enrollees.

- Third-parties **may not** make unsolicited calls to beneficiaries for non-MA and PDP products (for example, a "benefits compare" meeting) and provide those contacts to plans for ultimate use as an MA or PDP sales appointment.

- Sales of MA and PDP products are subject to CMS' scope of appointment guidance, even if conducted during a sales appointment for a Medigap policy.

Finally, for those outbound calls (refer to § 70.4, 70.6, and 80) that are allowable under these *Medicare Marketing* Guidelines, plan sponsors must comply to the extent applicable with the following:

- Federal Trade Commission's Requirements for Sellers and Telemarketers

- Federal Communications Commission rules and applicable State law

- National-Do-Not-Call Registry

- Honor "Do not call again" requests, and

- Abide by Federal and State calling hours

All outbound scripts utilized by the plan *sponsor* or its contractors must be submitted for review and approval prior to being used in the marketplace. When conducting outbound calls:

- Scripts must include a privacy statement clarifying that the beneficiary is not required to provide any information to the plan representative and that the information provided will in no way affect the beneficiary's membership in the plan. *Plans using outbound auto-dialing that is informational in nature will not be required to include the disclaimer in their scripts.*

- *Plan sponsors are prohibited from requesting beneficiary identification numbers (e.g., Social Security numbers, bank account numbers, credit card numbers, Health Insurance*

Claim number (HICN), and birthdates). NOTE: This policy does not extend to calls to existing members to conduct normal business related to enrollment in the plan.

- Plan sponsors are allowed to say they are contracted with Medicare to provide prescription drug benefits or that they are a Medicare-approved MA-PD plan/PDP.

- Plan sponsors **cannot** use language in outbound scripts that implies that they are endorsed by Medicare, calling on behalf of Medicare, or that Medicare asked them to call the member.

70.5.1 - Specific Guidance on Third-party Contact

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268(d), 423.2268(d)

Plan sponsors and their representatives are prohibited from engaging in direct unsolicited contact with potential enrollees, including outbound calls. This guidance applies to all downstream contractors, including third-party organizations utilized to generate sales leads and/or appointments. As such, plan sponsors should keep in mind that CMS views the following activities as out of compliance:

- Unsolicited MA plan or PDP marketing calls to beneficiaries (other than to current plan members if contracted by a plan, as previously described) to set up appointments with potential enrollees.

- Unsolicited calls to beneficiaries for non-MA and PDP products (for example, a "benefits compare" meeting) and providing those contacts to plans for ultimate use in an MA or PDP sales appointment.

Sales of MA and PDP products are subject to our scope of appointment guidance, even if conducted during a sales appointment for a Medigap policy. This includes the requirement for a beneficiary-completed agreement form prior to the appointment and a 48-hour waiting period.

Any plan sponsor or its representative that accepts an appointment to sell an MA or PDP product that resulted from an unsolicited contact with a beneficiary, regardless of who made the contact, will be in violation of the prohibition against unsolicited contacts.

70.6 - Outbound Enrollment and Verification Calls to All New Enrollees

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2272(b), 423.2272(b)

All plan sponsors are required to conduct outbound enrollment and verification (OEV) calls for enrollments effectuated by agents and brokers – including both independent and employed agents and brokers - to ensure individuals requesting enrollment understand the plan rules. It is important for the plan sponsor's sales staff to obtain from the applicant the best phone number to be used for verification and to provide a description of the enrollment verification process to the applicant during the application process.

OEV calls must be made to the applicant after the sale has occurred; they cannot be made at the point of sale. The plan sponsor must ensure that the verification calls are not conducted by sales agents and that sales agents are not physically present with the applicant at the time of the verification call. Plan sponsors may not use automated calling technologies to effectuate these outbound calls; the calls must be interactive. The plan sponsor must conduct these calls for all enrollment requests generated by agents and brokers (including both independent and employed agents and brokers). Excluded from this requirement are enrollments into employer or union sponsored plans, enrollments into PACE plans, enrollments submitted to plan sponsors by qualified State Pharmaceutical Assistance programs (SPAPs), and auto-enrollments, facilitated enrollments, and reassignments effectuated by CMS. Please note that if an individual with LIS makes an enrollment request that supersedes or changes a CMS-generated enrollment, and that election is effectuated by an agent or broker, the outbound verification requirements apply.

The outbound verification requirements apply to sales agents and other plan representatives only when they are acting in the role of sales agents and as such, are steering beneficiaries to one or a subset of all available plans. In other words, if a licensed agent is acting strictly as a customer service representative – that is, carrying out customer service duties such as providing factual information, or taking demographic information in order to complete an enrollment request at the initiative of an enrollee who has already decided to enroll in a plan – the outbound enrollment verification requirements do not apply. However, if there is steering and/or marketing by the CSR/agent and an enrollment request results, such an enrollment request is subject to the OEV requirements.

Plan-to-plan switches within an MA or Part D parent organization (both contract-to-contract and within contract) require outbound enrollment verification if the enrollment request involves a change in plan type or plan product (e.g., HMO to PPO, SNP HMO to non-SNP HMO). Plan-to-plan switches within an MA or Part D parent organization involving the same plan type or product type (e.g., PFFS to PFFS, DE SNP to DE SNP, PDP to PDP) are not subject to OEV requirements.

A model outbound enrollment verification call script is available at (http://www.cms.hhs.gov/ManagedCareMarketing/09_MarketngModelsStandardDocumentsandEducationalMaterial.asp#TopOfPage).

Refer to Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual for detailed information on outbound education and verification call requirements in the context of enrollment processing.

70.7 - Educational Events

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268(l), 423.2268(l)

Educational events are defined by the way in which an event is described to the Medicare beneficiary. An event hosted by the plan sponsor or an outside entity is considered an educational event if the event is advertised to beneficiaries as "educational." Educational events may not include any sales activities such as the distribution of marketing materials or the distribution or collection of plan applications.

The intent of this guidance is not to preclude plan sponsors from educating beneficiaries about their products; rather, it is to ensure that events that are advertised as "educational" comply with CMS' requirements. More specifically, plan sponsors may provide education at a sales or marketing event, but may not market or sell at an educational event.

The following are examples of acceptable materials and activities by plan sponsors or their representatives at an educational event:

- *Materials provided that meet the CMS definition of education; that is, informing a potential enrollee about MA or other Medicare programs, generally or specifically, but not steering, or attempting to steer, a potential enrollee towards a specific plan or limited number of plans. Specifically, any material distributed or made available to beneficiaries at an educational event must be free of plan-specific information (this includes plan-specific premiums, co-payments, or contact information), and any bias toward one plan type over another.*

- *A banner with the plan name and/or logo displayed (See § 40.7 and 50 for disclaimer guidance).*

- *Promotional items, including those with plan name, logo, and toll-free customer service number and/or website. Promotional items must be free of benefit information and consistent with CMS' definition of nominal gift.*

- *A business card if the beneficiary requests information on how to contact the plan or agent for additional information, as long as the business card is free of plan marketing or benefit information.*

- *Advertisements for the event may be distributed to either enrollees, non-enrollees, or both.*

- *Meals may be provided as described in § 70.2.1.*

- *Plan sponsors may participate in educational health fairs and health promotional events as either a sole sponsor or co-sponsor of an event hosted by*

multiple organizations as long as the event does not include a sales presentation and is billed as educational.

- *Respond to questions asked at an educational event. A response by plan sponsor's representative to questions will not render the event as sales/marketing provided no enrollment form is accepted.*

*Plan sponsors or their representatives **may not:***

- *Discuss plan-specific premiums and/or benefits.*
- *Distribute plan specific materials.*
- *Distribute or display business reply cards, scope of appointment forms, enrollment forms or sign-up sheets.*
- *Set up personal sales appointments or get permission for an outbound call to the beneficiary.*
- *Attach business cards or plan/agent contact information to educational materials; however, upon a request by the beneficiary a business card can be provided.*
- *Hold an educational event where participants are asked if they want information about a specific plan or limited number of plans.*
- *Accept enrollment forms. This included collecting completed enrollment forms or helping beneficiaries complete an enrollment form and then placing the form in a stamped envelope for the beneficiary to mail at a later date.*

The following are examples of events that are considered marketing/sales events, and are therefore subject to all guidance noted in § 70.8:

- *A plan sponsor advertises a presentation as educational, but after the presentation the agent asks if anyone would like to hear more about any specific options available to them. In this situation, the entire event would be considered a marketing/sales event. Similarly, a plan sponsor may not advertise an educational event and then have a marketing/sales event immediately following in the same general location (same hotel, for example).*
- *A plan sponsor conducts events where beneficiaries can get educational materials, a blood pressure check and enroll in the plan.*
- *An agent goes into a senior housing complex to talk about Original Medicare and/or Medigap policies, but then discusses an MA plan or PDP.*
- *An agent attends a community-sponsored health fair, and hands out plan-specific benefits information including premium and/or copayment amounts; or*

the agent hands out only educational materials but gives a brief presentation that mentions plan-specific premiums and/or copayment amounts.

- *A SHIP hosts an event that is not advertised to beneficiaries as "educational." A plan sponsor may be invited to discuss plan-specific benefits.*

70.8 - Marketing/Sales Events

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Marketing/sales events are defined by both the range of information provided and the way in which that content is presented to the Medicare beneficiary. In addition, marketing/sales events are defined by the plan's ability to collect applications and enroll Medicare beneficiaries during the event. There are two main types of marketing/sales events – formal and informal. All sales events are open to the general public and to all Medicare beneficiaries.

Note that if an event is scheduled as a marketing/sales event then requirements for marketing/sales events must be met, even if only one person is in attendance at the event.

Formal marketing/sales events are typically structured in an audience/presenter style with a sales person or plan representative formally providing specific plan sponsor information via a presentation on the products being offered. In this setting, the presenter usually presents to an audience that was previously invited to attend.

Informal marketing/sales events are considered marketing events and are usually conducted in a less structured presentation and/or environment to an audience and/or passersby. They typically utilize a table or kiosk manned by a plan sponsor representative who can discuss the merits of the plan's products.

Marketing/sales events allow a plan sponsor representatives to proactively discuss the merits of a plan or plan(s) to an interested beneficiary, whereas educational events only allow representatives to reactively answer questions posed by the interested party.

Plan sponsor marketing of non-health care related products (such as annuities and life insurance) to prospective enrollees during any MA or Part D sales activity or presentation is considered cross selling and is a prohibited activity. Beneficiaries already face difficult decisions regarding Medicare coverage options and should be able to focus on Medicare options without confusion or implication that the health and non-health products are a package. Plans may sell non-health related products on inbound calls when a beneficiary requests information on other non-health products. Marketing to current plan members of non-MA plan covered health care products, and/or non-health care products, is subject to HIPAA rules.

In addition, the following information, which applies to both formal and informal sales/marketing events, further distinguishes these marketing events from the other types of events outlined by CMS in these Medicare Marketing Guidelines.

At marketing/sales events plan sponsors may:

- *Distribute health plan brochures and enrollment advertising materials (including enrollment forms).*
- *Accept and perform enrollments.*
- *Formally present benefit information to the audience via a scripted talk, electronic slides, handouts, etc.*
- *Provide a scope of appointment form for a subsequent meeting; if a beneficiary requests a one-on-one meeting then the beneficiary must fill out a scope of appointment.*
- *Provide educational content to the audience or passersby.*
- *Provide a nominal gift to attendees with no obligation. Note that the value of any give-away, including entertainment, must be consistent with CMS' definition of nominal gift.*
- *Contribute cash towards prize money to a foundation or another entity if the event is jointly sponsored. The plan cannot claim to be the sole donor of the prize and it must be clear that the prize is attached to the event and not the individual organization.*

At marketing/sales events, plan sponsors must:

- *Announce all products/plan types that will be covered during the presentation at the beginning of that presentation (e.g., HMO, PFFS, MSA, etc).*
- *Submit all sales scripts and presentations for approval to CMS prior to their use during the marketing/sales event (see § 80 for additional information).*
- *Clearly read or state the following disclaimer during PFFS presentations/events:*
    - *For non-network PFFS plans: "A Medicare Advantage Private Fee-for-Service plan works differently than a Medicare supplement plan. Your provider is not required to agree to accept the plan's terms and conditions of payment, and thus may choose not to treat you, with the exception of emergencies. If your provider does not agree to accept our terms and conditions of payment, they may choose not to provide health care services to you, except in emergencies. If this happens, you will need to find another provider that will accept our terms and conditions of payment. Providers can find the plan's terms and conditions of payment on our website at: [insert link to PFFS terms and conditions of payment]."*

- *For full and partial network PFFS plans: "A Medicare Advantage Private Fee-for-Service plan works differently than a Medicare supplement plan. We have network providers (that is, providers who have signed contracts with our plan) for [[full network PFFS plan insert: all services covered under Original Medicare][partial network PFFS plans should indicate the category or categories of services for which network providers are available]]. These providers have already agreed to see members of our plan. If your provider is not one of our network providers, then the provider is not required to agree to accept the plan's terms and conditions of payment, and thus may choose not to treat you, with the exception of emergencies. If your provider does not agree to accept our terms and conditions of payment, they may choose not to provide health care services to you, except in emergencies. If this happens, you will need to find another provider that will accept our terms and conditions of payment. Providers can find the plan's terms and conditions of payment on our website at: [insert link to PFFS terms and conditions of payment]."*

- *Clearly explain the following during SNP presentations/events:*

  - *Eligibility limitations (e.g., required special needs status)*

  - *Special enrollment period (SEP) to enroll in, change or leave SNPs*

  - *Process for voluntary disenrollment if the beneficiary loses his/her Medicaid or institutional status (or becomes ineligible for the C-SNP)*

  - *A description of how drug coverage works with your plan.*

*At a marketing/sales event, plan sponsors **may not:***

- *Conduct health screening or other like activities that could give the impression of "cherry picking."*

- *Compare one plan sponsor to another by name unless both plan sponsors have concurred.*

- *Provide meals to attendees (refer to § 70.2.1 on exclusion of meals).*

- *Require beneficiaries to provide any contact information as a prerequisite for attending the event. Plans should clearly indicate on any sign-in sheets that completion of any contact information is optional.*

- *Plans sponsors may not ask beneficiaries to provide personal contact information in order to participate in a raffle or drawing. Plan sponsors should use other mechanisms (e.g., raffle tickets, random numbers) for conducting the drawings.*

- *Use prohibited statements at marketing/sales event (as stated in these Medicare Marketing Guidelines).*

Plan sponsors must upload all marketing/sales events prior to advertising the event (or prior to the event's scheduled date if there is no advertisement) but no later than the last day of the month prior to the event and can complete the upload requirement via HPMS. For detailed instructions, please refer to the "Marketing Events" section in the user guide of the HPMS Marketing module. Plan sponsors should follow these instructions to upload any marketing events in HPMS. Note that EGHP events that are only for EGHP members should be excluded from entry in HPMS.

In the Event Name field, plan sponsors should begin each Event Name field entry with either one of the following, followed by the actual event name:

- *Informal*
- *Formal*
- *Educational*

For example, "Informal: Walmart Kiosk"

Only formal and informal marketing/sales events are required to be uploaded into HPMS, and should now be named either "Formal" or "Informal" at the start of the Event Name Field.

Although plan sponsors are not required to submit educational events in HPMS, many organizations are choosing to do so. Plan sponsors that submit these types of events in HPMS should ensure that the term "educational" precedes the event name in the event name field.

Amendments to marketing/sales events (e.g. cancellations, changes of room and other updates and edits) must be updated in HPMS at least forty-eight (48) hours prior to the scheduled event. Plan sponsors should enter cancellations of marketing/sales events as soon as possible in the HPMS Marketing Module Events module. A functionality is available for both the "New Event" and "Update Events" data entry options. For detailed instructions, please refer to the "Marketing Events" section in the user guides for HPMS marketing module.

CMS has established the following requirements on how all plan sponsors should notify beneficiaries when advertised scheduled sales events have been cancelled. The method used to notify beneficiaries of the cancellation may vary depending on the individual plan's circumstances.

1. *If a sales event is cancelled within forty-eight (48) hours before its originally scheduled date and time, the plan sponsor must:*

    - *Notify its Regional Office Account Manager of the cancellation and cancel the event in HPMS.*
    - *Ensure a representative of the plan sponsor is present at the site of the cancelled sales event, at the time that the event was scheduled to occur, to inform attendees of the cancellation and distribute information about the plan*

sponsor. The representative should remain on site at least 15 minutes after the scheduled start of the event. If the event was cancelled due to inclement weather, a representative is not required to be present at the site.

2. If a sales event is cancelled more than forty-eight (48) hours before the originally scheduled date and time, the plan sponsor must notify beneficiaries of the cancellation by the same means the plan sponsor used to advertise the event. Plan sponsors must also notify the Regional Office Account Manager. Examples of reasonable notification are:

- *If an announcement of the sales event was made in the newspaper, then the cancellation of the event must also be announced through the same newspaper. If the newspaper's production and/or distribution schedule prohibits timely notification, the plan sponsor must provide evidence to the respective Account Manager (newspaper guidelines with submission timelines, run dates, etc.).*
- *If beneficiaries were identified through personal calls, then a representative of the plan sponsor must call the beneficiaries to inform them of the cancellation.*
- *If beneficiaries RSVP for the sales event, then a representative of the plan sponsor must call the beneficiaries to inform them of the cancellation.*
- *If an announcement of the sales event was sent through a mass mailing, then the plan sponsor should consult with the Regional Office to decide upon the most reasonable way to notify beneficiaries about the event cancellation in a short amount of time instead of a sending another mass mailing.*

Notification of cancelled sales events should be made, whenever possible, more than forty-eight (48) hours prior to the originally scheduled date and time of the event. If beneficiaries are notified of a cancellation more than 48 hours before the event, then there is no expectation that a representative of the plan sponsor will be present at the site of the event.

70.8.1 - Additional Guidance for Marketing Events in the Provider Setting

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268(j) and (k), 423.2268 (j) and (k)

As used in specific guidance about provider activities, the term "provider" refers to all providers contracted with the plan and its sub-contractors, including but not limited to, pharmacists, pharmacies, physicians, hospitals, and long-term care facilities.

These *Medicare Marketing* Guidelines are designed to guide plan sponsors and providers in assisting beneficiaries with plan selection, while at the same time striking a balance to ensure that provider assistance results in plan selection that is always in the best interest of the beneficiary. Providers that have entered into co-branding relationships with plan sponsors must also follow these guidelines.

70.8.2 - Plan Activities and Materials in the Health Care Setting

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268(k), 423.2268 (k)

Plan sponsors may not conduct sales activities in healthcare settings except in common areas. Common areas where marketing activities are allowed include areas such as hospital or nursing home cafeterias, community or recreational rooms, and conference rooms. If a pharmacy counter area is located within a retail store, common areas would include the space outside of where patients wait for services or interact with pharmacy providers and obtain medications.

Plan sponsors are prohibited from conducting sales presentations, distributing and accepting enrollment applications, and soliciting Medicare beneficiaries in areas where patients primarily intend to receive health care services or are waiting to receive health care services. These restricted areas generally include, but are not limited to, waiting rooms, exam rooms, hospital patient rooms, dialysis center treatment areas (where patients interact with their clinical team and receive treatment), and pharmacy counter areas (where patients interact with pharmacy providers and obtain medications). The prohibition against conducting marketing activities also applies after business hours in these settings. An example of this includes providers sending out authorization to their members, such as nursing home members, to request that the member give permission for a plan sponsor to contact them about available plan products (through mail, hand delivery or attached to an affiliation notice).

Only upon request by the beneficiary are plan sponsors permitted to schedule appointments with beneficiaries residing in long-term care facilities (including nursing homes, assisted living facilities, board and care homes, etc.). Providers are permitted to make available and/or distribute plan marketing materials as long as the provider and/or the facilities distributes or makes available plan sponsor marketing materials for all plans with which the provider participates. CMS does not expect providers to proactively contact all participating plans; rather, if a provider agrees to make available and /or distribute plan marketing materials they should do so knowing it must accept future requests from other plan sponsors with which it participates. Providers are also permitted to display posters or other materials within the long-term care facility and in admission packets announcing all plan contractual relationships. Long term care facility staff are permitted to provide residents that meet the I-SNP criteria an explanatory brochure for each I-SNP with which the facility contracts. The brochure can be explanatory about the qualification criteria and the benefits of being an I-SNP. The brochure may have a reply card or telephone number for the resident or responsible party to call to agree to a meeting or request additional information.

70.8.3 - Provider-Based Activities

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268(j), 423.2268(j)

CMS holds plan sponsors responsible for any comparative/descriptive material developed and distributed on their behalf by their contracting providers. The plan sponsor must ensure that any providers contracted (and its subcontractors, including providers or agents) with the plan sponsor comply with the requirements outlined in this chapter.

The plan sponsor must ensure that any providers contracted (including subcontractors or agents) with the plan sponsor to perform functions on their behalf related to the administration of the plan benefit, including all activities related to assisting in enrollment and education, agree to the same restrictions and conditions that apply to the plan sponsor through its contract. In addition, the plan sponsor (and subcontractors, including providers or agents) are prohibited from steering, or attempting to steer an undecided potential enrollee toward a particular provider, or limited number of providers, offered either by the plan sponsor or another plan sponsor, based on the financial interest of the provider or agent (or their subcontractors or agents). *While conducting a health screenings, providers may not distribute plan information to patients since both activities are prohibited marketing activities.*

CMS is concerned with provider activities for the following reasons:

- Providers may not be fully aware of all plan benefits and costs; and
- Providers may confuse the beneficiary if the provider is perceived as acting as an agent of the plan versus acting as the beneficiary's provider.

Providers may face conflicting incentives when acting as a plan sponsor representative. For example, some providers may gain financially from a beneficiary's selection of one plan over another plan. Additionally, providers generally know their patients' health status. The potential for financial gain by the provider influencing a beneficiary's selection of a plan could result in recommendations that do not address all of the concerns or needs of a potential plan enrollee.

Beneficiaries often look to health care professionals to provide them with complete information regarding their health care choices (e.g., providing objective information regarding specific plans, such as covered benefits, cost sharing, drugs on formularies, utilization management tools, and eligibility requirements for SNPs). To the extent that a provider can assist a beneficiary in an objective assessment of the beneficiary's needs and potential plan sponsor options that may meet those needs, providers are encouraged to do so. To this end, providers may certainly engage in discussions with beneficiaries when patients seek information or advice from their provider regarding their Medicare options.

All payments that plans make to providers for services must be fair market value, consistent for necessary services, and otherwise comply with all relevant laws and regulations, including the Federal and any State anti-kickback statute.

For enrollment and disenrollment guidance related to beneficiaries residing in long-term care facilities (e.g., enrollment period for beneficiaries residing in long-term care facilities and use of personal representatives in completing an enrollment application), please refer to Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the *Medicare* Prescription Drug Benefit Manual.

Providers should remain neutral parties in assisting plan sponsors with marketing to beneficiaries or assisting with enrollment decisions. Providers not being fully aware of plan benefits and costs could result in beneficiaries not receiving information needed to make an informed decision about their health care options. Therefore, it would be inappropriate for providers to be involved in any of the following actions:

- Offering sales/appointment forms.
- Accepting enrollment applications for MA/MA-PD plans or PDPs.
- Directing, urging or attempting to persuade beneficiaries to enroll in a specific plan based on financial or any other interests.
- Mailing marketing materials on behalf of plan sponsors.
- Offering anything of value to induce plan enrollees to select them as their provider.
- Offering inducements to persuade beneficiaries to enroll in a particular plan or organization.
- *Health screening and distributing information to patients, are prohibited marketing activities.*
- Accepting compensation directly or indirectly from the plan for beneficiary enrollment activities.

Providers contracted with plan sponsors (and their contractors) are permitted to do the following:

- Provide the names of plan sponsors with which they contract and/or participate (See § 70.8.4 for additional information on affiliation.)
- Provide information and assistance in *applying for the LIS.*
- *Make available and/or distribute plan marketing materials for a subset of contracted plans only as long as providers offer the option of making available and/or distributing marketing materials to all plans with which they participate. CMS does not expect providers to proactively contract all participating plans to solicit the distribution of their marketing materials: rather, if a provider agrees to make available and/or distribute plan marketing materials for some of its contracted plans, it should do so knowing it must accept future requests from other plan sponsors with which it participates. To that end, providers are permitted to:*
    - *Provide* objective information on plan sponsors' specific plan formularies, based on a particular patient's medications and health care needs.

- *Provide objective information regarding plan sponsors' plans, including information such as covered benefits, cost sharing, and utilization management tools.*

- *Make available and/or distribute plan marketing materials including PDP enrollment applications, but not MA or MA-PD enrollment applications for all plans with which the provider participates.*

- *To avoid an impression of steering, providers should not deliver materials/applications within an exam room setting.*

- *Refer their patients to other sources of information, such as SHIPs, plan marketing representatives, their State Medicaid Office, local Social Security Office, CMS' website at http://www.medicare.gov/. or 1-800-MEDICARE.*

- *Print out and share information with patients from CMS' website.*

Providers are permitted to make available and/or distribute plan marketing materials for a subset of contracted plans only as long as providers offer the option of making available and/or distributing marketing materials to all plans with which they participate. CMS does not expect providers to proactively contact all participating plans to solicit the distribution of their marketing materials: rather, if a provider agrees to make available and /or distribute plan marketing materials for some of its contracted plans, it should do so knowing it must accept future requests from other plan sponsors with which it participates.

The "Medicare and You" Handbook or "Medicare Options Compare" (from http://www.medicare.gov), may be distributed by providers without additional approvals. There may be other documents that provide comparative and descriptive material about plans, of a broad nature, that are written by CMS or have been previously approved by CMS. These materials may be distributed by plan sponsors and providers without further CMS approval. This includes CMS *Medicare Prescription Drug* Plan Finder information via a computer terminal for access by beneficiaries. Plan sponsors should advise contracted providers of the provisions of these rules.

70.8.4 - Provider Affiliation Information

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Providers may announce new affiliations and repeat affiliation announcements for specific plan sponsors through general advertising (e.g., publicity, radio, television). An announcement to patients of a new affiliation which names only one plan sponsor may occur only once when such announcement is conveyed through direct mail and/or e-mail. Additional direct mail and/or e-mail communications from providers to their patients regarding affiliations must include all plans

with which the provider contracts. Provider affiliation banners, displays, brochures, and/or posters located on the premises of the provider must include all plan sponsors with which the provider contracts. *Providers are permitted to display posters or other materials announcing only a subset of all plan contractual relationships as long as providers offer the option of displaying posters or other materials to all plans with which they participate. CMS does not expect providers to proactively contact all participating plans to solicit their inclusion on posters or other materials announcing plan contractual relationships; rather, if a provider agrees to list on posters or other materials announcing plan contractual relationships some of its contracted plans, it should do so knowing it must accept future requests from other plan sponsors with which it participates.*

Any affiliation communication materials that describe plans in any way (e.g., benefits, formularies) must be approved by CMS. Multiple plan sponsors can either have one plan sponsor submit the material on behalf of all the other plan sponsors, or have the piece submitted and approved by CMS for each plan sponsor mentioned prior to use. Materials that indicate the provider has an affiliation with certain plan sponsors and that only list plan names and/or contact information does not require CMS approval.

70.8.5 - SNP Provider Affiliation Information

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Providers may feature SNPs in a mailing announcing an ongoing affiliation. This mailing may highlight the *provider's* affiliation or arrangement by placing the SNP affiliations at the beginning of the announcement and may include specific information about the SNP. This includes providing information on special plan features, the population the SNP serves or specific benefits for each SNP. The announcement must list all other SNPs with which the provider is affiliated.

70.8.6 - Comparative and Descriptive Plan Information

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Providers may distribute printed information provided by a plan sponsor to their patients comparing the benefits of all of the different plans with which they contract. Materials may not "rank order" or highlight specific plans and should include only objective information. Such materials must have the concurrence of all plan sponsors involved in the comparison and must be approved by CMS prior to distribution (e.g., these items are not be subject to File & Use). The plan sponsor must determine a lead plan to coordinate submission of these materials (refer to § 90.2 for more information).

NOTE: Plan sponsors may not use providers to distribute printed information comparing the benefits of different plans unless providers accept and display materials from all plan sponsors in the service area and contract with the provider.

70.8.7 - Comparative and Descriptive Plan Information Provided by a Non-Benefit/Service Providing Third-Party

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Providers may distribute printed information comparing the benefits of different plan sponsors (all or a subset) in a service area when the comparison is done by an objective third party. For more information on non-benefit/service providing third party providers, refer to § 40.14.6.

70.8.8 - Providers/Provider Group Websites

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Providers may provide links to plan enrollment applications and/or provide downloadable enrollment applications. The site must provide the links/downloadable formats to enrollment applications for all plan sponsors with which the provider participates. As an alternative, providers may include a link to the CMS Online Enrollment Center.

NOTE: *The preceding requirement is not applicable to certain plan types such as section 1876 cost plans, Medicare MSAs, 800-series employer group waiver plans, and Religious Fraternal Benefit plans. SNPs may use the links, and the SNP should notify the provider that they may use the OEC link if they choose to but that it is not required.*

70.9 - Personal/Individual Marketing Appointments

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

Personal/individual marketing appointments are defined by the intimacy *of the appointment's location (e.g., the setting or environment*). Personal/individual marketing appointments typically take place in the Medicare beneficiary's home, however, these appointments can also take place in other venues such as a library or coffee shop.

If the appointment was set up in accordance with the scope of appointment guidance provided in the next section, the sales person may:

- Distribute plan materials (***we*** encourage plan sponsors to provide the ***enrollment kit in*** one-one appointments, if not, then inform beneficiary on how to access the document through other means (e.g., mail, website).
- Discuss various plan options
- Provide educational content
- Provide and collect enrollment forms

The sales person, however, **may not** do the following:

- *Discuss plan options that were NOT agreed to by the Medicare beneficiary (see scope of appointment information in § 70.9.1).*
- *Market non-health care related products (such as annuities, life insurance or VAIS.)*
- *Ask a beneficiary for referrals.*
- Solicit/accept an enrollment request (application) for a January 1st effective date prior to the start of the Annual Enrollment Period (AEP) unless the beneficiary is entitled to a Special Election Period (SEP) or within their initial coverage election period/initial enrollment period.

70. 9.1 - Scope of Appointment

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

422.2268(g) and (h), ***423.2268 (g) and (h)***

In conducting marketing activities, an MA or Part D plan sponsor may not market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment. Distinct lines of plan business include Medigap, MA, and PDP products.

The scope of appointment must be agreed to by the Medicare beneficiary prior to any face-to-face personal/individual marketing appointment. Agents and brokers can document the scope of appointment in writing via a scope of appointment form. If the scope of appointment is being documented by recording a phone call in advance of the appointment, the call should be placed by the plan sponsor and not the agent/broker. The sales person is bound to only discuss during that appointment those products that have been agreed upon by the beneficiary during that appointment. If other products need to be discussed at the request of the beneficiary, a second scope of appointment form must be completed for the new product type and then the marketing appointment may be continued. Upon CMS request, the plan sponsor must be able to produce documentation.

For example, if a beneficiary has agreed to an in-home appointment to discuss a PDP product, an agent can discuss an HMO product with them during that same meeting, if the beneficiary

requests it and a new scope of appointment form is completed. To further clarify the requirements around written documentation:

- *Plan sponsors must secure scope of appointment documentation prior to the appointment. A beneficiary cannot agree to the scope over the phone (unless it is recorded) and then sign the documentation form at the beginning of the sales appointment. Any scope of appointment form must be completed by the beneficiary and returned prior to the appointment. If it is not feasible for the scope of appointment form to be executed prior to the appointment, an agent may have the beneficiary sign the form at the beginning of the marketing appointment. However, CMS expects plans to record and maintain documentation on why it was not feasible to obtain the scope of appointment prior to the appointment.*

- The documentation must be in writing, in the form of a signed agreement by the beneficiary, or a recorded oral agreement. A plan sponsor or agent documenting the agreement is not acceptable *for purposes of meeting this requirement,* whether done in writing or using an electronic contact documenting system.

- Plan sponsors are allowed and encouraged to use a variety of technological means to fulfill the scope of appointment requirement, including conference calls, fax machines, designated recording line, pre-paid envelopes*, and* e-mail, etc.

- A beneficiary may sign a scope of appointment form at a marketing presentation for a follow-up appointment. In these instances, the 48 hour waiting period does not apply. For example, if a beneficiary attends a marketing presentation, and, *after* the presentation, requests an individual appointment, the sales person can arrange for that appointment to take place immediately following the sales presentation provided the beneficiary has completed the scope of appointment form.

Marketing/sales events, as described in § 70.8. do not require documentation of beneficiary agreement because the scope of products that will be discussed should be indicated on all event advertising materials. CMS has developed a model scope of appointment form which *is posted at* http://www.cms.hhs.gov/ManagedCareMarketing/09_MarketngModelsStandardDocumentsandEducationalMaterial.asp#TopOfPage). Written scope of appointment forms must be submitted *in HPMS under* Category 4000, Code 4011. We encourage plan sponsors to use our model scope of appointment form. Use of the model without modification may be submitted under File & Use. A modified form must be submitted for forty-five (45)-day review. If the scope of appointment is gathered via a recorded phone call the plan sponsor must ensure that any associated scripts for such calls must be submitted to and approved by CMS prior to their use.

70.9.2 - Beneficiary Walk-ins to a Plan or Agent/Broker Office or Similar Beneficiary-Initiated Face-to-Face Sales Event

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268(g) and (h), 423.2268 (g) and (h)

In instances where a beneficiary visits a plan or an agent/broker office on his/her own accord, the plan sponsor or agent/broker should complete a scope of appointment form and secure the beneficiary's signature prior to discussing MA, PDP, *or cost* plans. Plan sponsors and agents/brokers should note on the scope of appointment form that the beneficiary was a walk-in. In this instance, the forty-eight (48) hour waiting period does not apply.

70.10 - Specific Guidance on Outreach to Dual Eligible Members

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264(a)(4), 423.2264(a)(3)

This section provides guidance to plan sponsors on dual eligible outreach program requirements and the process for submitting outreach program details and outreach materials (e.g., letters, call scripts) to CMS for approval. In addition, this section also provides CMS staff with operating procedures for reviewing and approving the outreach programs.

A number of plan sponsors' enrolled members are, due to financial status, eligible for State financial assistance through State Medicaid Programs. This assistance provides them an array of financial savings ranging from partial payment of Medicare Part B premiums to full payment of Medicare premiums and other plan cost sharing. Historically, some of those eligible do not apply for these State savings programs because:

- The individuals equate Medicaid with welfare and associate a social stigma with the terms;
- They are not aware of the savings that are available;
- They do not understand the eligibility requirements; or
- They find the process sometimes complex and difficult to understand.

Some plan sponsors choose to conduct outreach to their members to educate them and to assist them in applying for these savings programs. This may be especially true because CMS capitates plan sponsors at a higher rate for some dual eligible members. Because of the potential benefits to both the members and plan sponsors CMS encourages but does not require plan sponsors to assist their members with applying for State financial assistance.

70.10.1 - Guidance on Dual Eligibility

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264(a)(4), 423.2264(a)(3)

There are several categories of dual eligibility, each having specific income requirements and providing different levels of financial assistance to those who qualify at that level. Specific information on categories and amounts ***is*** available at http://www.cms.hhs.gov/DualEligible/.

70.10.2 - Guidance for Dual Eligible Outreach Program

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264, 422.2268, 423.2268

In order to assure CMS that each plan sponsor's outreach programs effectively assist members while protecting them from undue pressures or privacy violations, plan sponsors – *including any contracted entity conducting outreach on behalf of the plan sponsor – mus*t adhere to the following guidance.

Plan sponsors *and their contracted entities conducting outreach on their behalf* must:

- Ensure that all outreach materials meet all applicable Medicare Advantage *M*arketing *G*uidelines *requirements* that apply to materials outside the dual eligible outreach category as described throughout this guidance.

- Provide outreach to all levels of dual eligibles, including those levels that do not provide plan sponsors with additional capitation amounts from CMS. All outreach materials and telephone scripts must include eligibility information that includes the QI-1 level as described at http://www.cms.hhs.gov/DualEligible/.

- Clarify in outreach materials that the member may voluntarily offer information, including financial information, but that the member is not obligated to provide this information. However, information *regarding Medicaid status* is needed to confirm eligibility *for a DE SNP*.

- Clarify in outreach materials and discussions with members that the member's failure to provide information will in no way adversely affect the beneficiary's membership in his or her health plan but *that Medicaid status will* be needed to confirm eligibility for a *DE* SNP.

- Clarify in outreach materials, to include member letters, that the Medicare Savings Programs are part of either the "State Medicaid program" or "State medical assistance programs."

- State in materials and discussions with members that the plan sponsor will not share the information with any other entity not directly associated with determining eligibility or under contract to participate in the outreach process.

- Clarify in outreach materials that the plan sponsor is only providing an initial eligibility screening and that only the appropriate State Agency can make a final eligibility determination.

- Provide guidance to a member on how to proceed with the application process even if the plan sponsor's screening process indicates that the member is probably not eligible for assistance under any of the dual eligibility programs.

- Provide adequate training to staff conducting the outreach. If the plan sponsor subcontracts this effort to another entity, it must ensure that the subcontractor's staff is adequately trained to provide outreach.

- Include alternate sources of information in outreach materials; *member* letters and/or brochures that contain outreach information telephone numbers must also include the telephone number for beneficiaries to call the SHIP and the appropriate State Agency. Outreach materials may also include the telephone number for the 1-800-MEDICARE (1-800-633-4227) and the TYY number for Medicare (1-800-486-2048).

- Include privacy guidelines in outreach materials, telephone scripts, and internal processes and/or contracts with entities performing outreach for the plan sponsor. Contractual privacy guidelines must clearly state that all financial information collected from members of the plan sponsor will not be used for any other purpose by the entity collecting the data. Privacy guidelines must also state that entities involved in the outreach will not share member information with anyone not involved in the outreach process.

- Ensure that contracts with entities taking part in some aspect of outreach activities meet Medicare Advantage Administrative Contracting requirements listed in the Medicare Managed Care Manual, Chapter 11, and § 100.5.

- *Work closely with CMS' Regional Office staff during the outreach submission and review process so that CMS can work cooperatively with stakeholders (e.g., SHIPs, State Agency) to ensure better education and preparation prior to the outreach process initiation.*

- *Communicate directly with stakeholders (e.g., SHIPs, State Agency) to ensure better education and preparation prior to the outreach initiation process.*

The plan sponsor may:

- Conduct outreach for only a portion of its plan membership. Selection of the focus population may be based upon demographic data and/or may focus on a specific geographic area. However, the plan sponsor must provide outreach to all individuals within those pre-identified population segments. Additionally, if the plan sponsor receives an inquiry from a plan member not previously identified in

the targeted group, it must provide assistance to that member as if he or she had been included in the initial group.

- Provide hands-on assistance to the member in completing all necessary applications for financial assistance including submitting the paperwork to the appropriate State office. This assistance can be in the member's home only if the member requests such a visit.

- Use the "Authorization to Represent" form limited to the specific purposes of completing and submitting paperwork on behalf of the member, discussing the member's case with case workers, and gathering information from and on behalf of the plan sponsor's member. The "Authorization to Represent" form must specify that the authorization is limited to securing benefits under "the Medicare Savings Program" or "the Medicaid Program" and **cannot** extend to other programs unless agreed upon and noted by the member. "Authorization to Represent" shall not give the outreach specialist the authority to sign any documents on behalf of the member, make any enrollment decisions for the member, or file a grievance or request an initial decision (coverage determination) or appeal on a member's behalf.

- Follow up with members who do not respond to the initial member letter. This follow-up may be in the form of a second and/or third letter or telephone calls. If the member does not respond to the third effort, the plan sponsor must refrain from contacting the member for at least six months following the last outreach attempt.

- Provide assistance to members reapplying for financial benefits if and when required to do so by the Medicaid State agency.

- Subcontract all outreach efforts to another entity or entities. In such cases, while the plan sponsor retains all responsibility for meeting CMS' requirements, *and* must submit all documentation to the appropriate CMS Regional Office for approval *per the submission guidance provided later in this section.*

The plan sponsor **must not**:

- Conduct door-to-door solicitation or outreach prior to receiving an invitation from the member to provide assistance in his or her home.

- Share any member information, financial or otherwise, with any entity not directly involved in the outreach process.

- Store or use member financial information for any purpose other than the initial screening eligibility, the submission and follow-up of an application for benefits, for recertification purposes, and as required by law.

- Contact any member who has refused outreach assistance or who has not responded to the telephone call or follow-up letter until at least six months following the last outreach attempt.

- Imply in any written materials or other contact with the member that the organization has the authority to determine the member's eligibility for State assistance programs.

70.10.3 - Outreach Submission Requirements

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

In general, plan sponsors either develop and conduct their own outreach or contract with an external entity to provide the expertise, materials, and member assistance. Regardless of the approach, plan sponsors must submit the following information to their Regional Office Account Manager.

In electronic format, using the US Postal Service or other delivery method;

1. A detailed description of each step in the outreach process and the entity responsible for each step. (CMS recommends a flow chart showing the result of each action.)
2. A timeline showing the proposed dates of outreach activities, the number of members involved in each activity, and the service area (e.g., county) included in the activities. This is to allow CMS to more accurately coordinate outreach activities with its partners (e.g., SHIPs, State Agencies).
3. Executed contracts with all external entities involved in the outreach process. This includes contracts with any subcontractors taking part in the activities.
4. Supporting documentation from the appropriate State Agency providing specific State income requirements for each savings program level, and names and contacts within the appropriate State Agency/agencies.
5. *Internal training programs the organization is using to educate staff involved in outreach.*
6. *An internal plan for protecting the confidentiality of the member's financial or other personal information gathered in the outreach process.*
7. Outreach letters and other materials (e.g., brochures, Authorization to Represent form) going to plan sponsor members.
8. Telephone scripts or other outreach assistance scripts that will guide representatives in answering members' questions or discussing the assistance available to them. Such scripts must include a privacy statement clarifying that the member is not required to provide any information to the representative and that the information provided will in no way affect the beneficiary's membership in the plan.

In some instances, a plan sponsor may choose to submit an outreach proposal that CMS has already approved for use by another plan sponsor or an outreach proposal that will be used by other plan sponsors in the future. This is common when a plan sponsor is part of a national

organization with multiple contracts, each of which is conducting its own outreach but sharing the same outreach materials. This is also common when a plan sponsor conducts its own outreach efforts through a subcontracting entity that provides the same services and outreach materials to multiple plan sponsors.

If a plan sponsor submits an outreach proposal that CMS previously approved on or after April 1, 2002 that does not contain substantive changes to qualify it as an "initial" proposal, the plan sponsor must submit the items listed above (1-8). In addition the plan sponsor must submit an attestation from either itself or its contracted outreach vendor stating: (1) that the proposal has been approved by CMS, (2) the date of that approval, and (3) that the new submission does not contain substantive changes to the approved program.

70.10.4 - CMS Review/Approval of Outreach Process

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

The CMS review process for new outreach proposals differs from the review process for previously approved outreach proposals. The processes for both submissions are detailed in § 70.10.5.

70.10.5 - Reviewing New Outreach Programs

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 422.2264, 422.2268, 423.2262, 423.2264, 423.2268

The plan sponsor is responsible for submitting the outreach proposal to CMS and working with CMS through the review and approval process even if a subcontractor developed the proposal. CMS will hold the plan sponsor fully responsible for all the provisions of the outreach program and for assuring the members of their rights and protections outlined in the MA program regulations.

Because CMS considers outreach materials to be a form of marketing, CMS will review outreach proposals according to current time frames for reviewing marketing material. CMS will conduct its initial review and provide comments to the plan sponsor within forty-five (45) days of receipt of a new (not previously approved) proposal. At this time, the plan sponsor should not submit this material through HPMS but as a separate filing outside the "normal" marketing material submission process.

Plan sponsors must submit one complete copy (paper and electronic) of the materials to the CMS Regional Office Account Manager. If a proposal incorporates additional State(s) that impact another CMS Regional Office, then the Regional Office Account Manager who received the

request will coordinate the review with the other affected Regions and the CMS State Representative for those State(s).

The Regional Office Account Manager will relay CMS comments back to the plan sponsor, gather revisions (when necessary), and finish the review and approval process based upon the plan sponsor's revisions. The Regional Office Account Manager will share outreach materials with the appropriate CMS State Representatives. The CMS State Representatives should, at a minimum, share the member letters with the State Agency as a way to verify the accuracy of the information contained in the proposal and to receive input from State partners. Upon final approval of the proposal and outreach materials, the Regional Office Account Manager will send an approval letter to the plan sponsor.

The Regional Office will then contact its partners (SHIPs, State Medicaid Offices) to notify them of the outreach effort and possible increase in beneficiary inquiries. The Regional Office will share copies of outreach letters with the State Agencies to prepare them for incoming questions.

70.10.6 - Reviewing Previously Approved Outreach Programs

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

If a plan sponsor submits an outreach proposal that CMS has already approved and that does not contain substantive changes, then the CMS Regional Account Manager, in conjunction with the appropriate CMS State Representatives, will only review the targeted membership information (audience number and outreach dates), the contract(s) between the plan sponsor and its outreach subcontractor(s), the updates to benefit levels and income and resource criteria, and the attestation. CMS will respond to the plan sponsor within the ten (10) day time frame CMS has established for reviewing standardized marketing materials. CMS' Regional Office will file the outreach proposal for future reference. CMS recognizes that the plan sponsor will have to make simple periodic changes to its outreach programs in order to update minimum income levels. As stated previously CMS does not consider these updates to be "substantive changes" in that they do not prompt a full review of an outreach proposal. However, the plan sponsor is still responsible for submitting such changes to the appropriate lead CMS Regional Office for marketing reviews to ensure accuracy of such changes.

If the plan sponsor wishes to make substantive changes to the outreach process, it must submit those changes to the appropriate CMS Regional Office Account Manager for review according to the review process above.

70.11 - PFFS Plan Provider Education and Outreach Programs

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.114(a)(1)

CMS strongly encourages all PFFS plan sponsors to develop and implement a provider education and outreach program to encourage a wide range of providers to accept PFFS enrollees. PFFS plan sponsors must develop provider relation strategies, a provider education process, and educational materials that include establishing relationships with and educating providers in the PFFS plan's service area. PFFS plan sponsors must conduct effective outreach to providers to help them understand how PFFS plans work and to overcome any resistance that may be particularly caused by concerns about the timeliness and accuracy of payments. In order to address these issues, PFFS plan sponsors must ensure that they clearly inform providers about how to obtain their terms and conditions of payment, how to get payment or coverage questions quickly answered, and how to appeal payment decisions.

Following are examples of practices that CMS encourages PFFS plan sponsors to incorporate in their provider education and outreach programs. In addition, there may be other approaches that PFFS plan sponsors may utilize in order to develop provider education and outreach programs.

- Use the appropriate staff (e.g., provider relations specialists) to educate providers in the plan's service area and State provider associations (e.g., medical and hospital associations).

- Furnish a provider educational material packet to providers who contact the plan for information. The contents of the provider education material packet could include the plan's terms and conditions of payment, the beneficiary/provider education leaflet and the CMS provider education letter. Refer to the web link http://www.cms.hhs.gov/PrivateFeeforServicePlans/.

- Furnish a provider educational material packet to providers within the plan sponsor's service area who have not already received a packet, upon receipt of the first claim.

- Develop a process to obtain current provider information from prospective and current enrollees and proactively contact and educate the enrollee's current providers. These providers can be furnished with a provider educational material packet.

- Ensure the beneficiary/provider education leaflet is widely available to enrollees, so that they may in turn furnish it to their providers.

- Non-network PFFS plan sponsors have the option of establishing direct contracts under which providers agree in advance to treat plan members and accept the plan's terms and conditions of payment. PFFS plan sponsors that establish payment rates less than Original Medicare must have direct contracts with sufficient providers in order to meet Medicare access requirements under federal regulations at 42 CFR 422.114(a)(2)(ii) or (a)(2)(iii). However, PFFS plan sponsors that have met Medicare access requirements by establishing payment rates at or above Original Medicare may also establish direct contracts with providers. In this case, the plan sponsor establishes provider contracts not to meet Medicare access requirements, but rather to ensure enrollees that they will have access to providers who will agree to accept the PFFS plan.

Plan sponsors should focus on increasing outreach to providers and educating them about how PFFS plans work. To encourage provider participation, plan sponsors must ensure that providers

have reasonable access to their terms and conditions of payment and that those providers are being paid correctly and timely. *At a minimum, plans should prominently display their terms and conditions on their website.* CMS will be closely monitoring beneficiary and provider complaints and other marketplace-based information to determine whether compliance and/or enforcement actions are warranted. CMS may require that PFFS plan sponsors with documented provider access problems provide CMS data about their provider education and outreach efforts.

70.11.1 - PFFS Plan Staff Requirement for Assisting Providers

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.114

PFFS plan sponsors are required to have staff available to assist providers with questions concerning plan payment and payment accuracy. CMS encourages PFFS plan sponsors to better educate their provider relations staff on the rules of their terms and conditions of payment so that they can provide reliable information to providers accurately and quickly. Plan sponsors must be committed to providing accurate information to providers that is also easily accessible. For example, providers should be able to obtain accurate information on member cost sharing amounts (including applicable deductibles) and plan payment rates when they call the plan. PFFS plan sponsors should address in a timely manner any inadequate capacity of plan contacts, such as excessive busy signals or excessive lack of timely response to voicemail messages.

70.11.2 - PFFS Plan Terms and Conditions of Payment Contact and Website Fields in HPMS

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.114

Fields are available in HPMS to allow MAOs offering PFFS plans to directly provide CMS with their plan terms and conditions of payment provider contact information. All PFFS plan sponsors must complete the data entry for these fields in HPMS and update the information as needed.

CMS has added the following contact field in HPMS for PFFS plan sponsors: “PFFS Terms and Conditions of Payment Contact for Public website.” Note that this field should be populated with the contact that will facilitate provider access to the MAO’s PFFS plan terms and conditions of payment. Use the following navigation path in HPMS to enter the appropriate information for this new contact: HPMS Homepage > Contract Management > Contract Management > Select a Contract Number > Contact Data.

CMS has also added the following website field in HPMS for PFFS plans: “PFFS Terms and Conditions of Payment website.” Note that this field should be populated with the web address for where the MAO maintains its PFFS plan terms and conditions of payment. Use the following navigation path in HPMS to enter the appropriate information for this new web address: HPMS

Homepage > Contract Management > Basic Contract Management > Select a Contract Number > Org. Marketing Data.

80 - Special Guidance on Telephonic Activities and Scripts

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

80.1 - Customer Service Call Center Requirements

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.112 (a)(7) (i) & (ii), 423.128(d)(1)

During the annual enrollment period (November 15 to December 31 in 2010 for CY 2011; October 15 to December 7 for CY 2012 and beyond) through sixty (60) days past the beginning of the following calendar year (January 1 to March 1), all plan sponsors are required to operate a toll-free call center for both current and prospective enrollees that operates seven days a week at least from 8:00 A.M. to 8:00 P.M. according to the time zones for the regions in which they operate. During this time period, current and prospective enrollees must be able to speak with a live customer service representative.

From March 2 until the following annual enrollment period, plan sponsors are still required to operate a toll-free call center for both current and prospective enrollees that operate from 8:00 A.M. to 8:00 P.M. However, during this time for Saturdays, Sundays, and holidays, plan sponsors are permitted to use alternative technologies to meet the customer service call center requirements. For example, a plan sponsor may use an interactive voice response system or similar technologies to provide the required information listed below, and/or allow a beneficiary to leave a message in a voice mail box. A customer service representative must then return the call in a timely manner, no more than one business day later.

Call centers must meet the following operating standards:

- Provide information in response to inquiries outlined in § 80.1.3.
- Follow an explicitly defined process for handling customer complaints.
- Provide service to all non-English speaking and hearing impaired beneficiaries.
- Make information about Best Available Evidence (BAE) policy readily available for those who contact the plan sponsor’s call center. Refer to § 100.3 for additional information.

Call centers must meet the following operating standards:

- Average hold time must not exceed two (2) minutes. The average hold time is defined as the average time spent on hold by a caller following an interactive voice response (IVR) *system* and before reaching a live person.

- Eighty (80) percent of incoming calls must be answered within thirty (30) seconds.

- Disconnect rate of all incoming calls must not exceed five (5) percent.

80.1.1 - Pharmacy Technical Help Call Center Requirements

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.128(d)(1)

Plan sponsors offering Part D coverage must operate a toll-free pharmacy technical help call center or make available call support to respond to inquiries from pharmacies and providers regarding the beneficiary's Medicare prescription drug benefit. This requirement can be accommodated through the use of on-call staff pharmacists or by contracting with the organization's PBM during non-business hours as long as the individual answering the call is able to address the call at that time. Inquiries will concern such operational areas as claims processing, benefit coverage, claims submission and claims payment. The call center must operate or be available during the entire period in which the plan sponsor's network pharmacies in its plans' service areas are open.

Please note that plan sponsors whose pharmacy networks include twenty-four (24) hour pharmacies must operate their pharmacy technical help call centers twenty-four (24) hours a day as well.

The pharmacy technical help call center must meet the following operating standards:

- *Average hold time must not exceed two (2) minutes. The average hold time is defined as the average time spent on hold by a caller following an interactive voice response (IVR) system and before reaching a live person.*
- Eighty (80) percent of incoming calls must be answered within thirty (30) seconds.
- Disconnect rate of all incoming calls must not exceed five (5) percent.

80.1.2 - Coverage Determinations and Appeals Call Center Requirements

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111(b)(8), 423.128(d)(1) 423.566(a)

All plan sponsors must operate a toll-free call center with a live customer service representatives available to respond to physicians and other providers for information related to coverage determinations (including exceptions and prior authorizations), and beneficiary Part D appeals.

The call center must operate during normal business hours and never less than from 8:00 a.m. to 6:00 p.m., Monday through Friday, according to the time zones for the regions in which they operate. Plan sponsors are expected to accept requests for coverage determinations/redeterminations outside of normal business hours, but are not required to have live customer service representatives available to accept such requests outside normal business hours. Additional details are available in Chapter 18 of the Prescription Drug Benefit Manual.

Voicemail may be used *outside of normal business hours* provided the message:

- Indicates that the mailbox is secure.
- Lists the information that must be provided so the case can be worked (e.g., provider identification, beneficiary identification, type of request (coverage determination or appeal), physician support for an exception request, and whether the member is making an expedited or standard request.
- For coverage determination calls (including exceptions requests), articulates and follows a process for resolution within twenty-four (24) hours of call for expedited requests and seventy-two (72) hours for standard requests.
- For appeals calls, information should articulate the process information needed and provide for a resolution within seventy-two (72) hours for expedited appeal requests and seven (7) calendar days for standard appeal requests.
- Provides and follows a process for immediate access in situations where an enrollee's life or health is in serious jeopardy.

80.1.3 - Required Scripts for Inbound Informational Calls

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

Inbound informational/customer service telephone scripts are considered marketing materials and are subject to all requirements in this section and other relevant sections of the Medicare Marketing Guidelines. Refer to § 170 for more information about allowable uses of beneficiary information that is applicable to § 80.1.3-80.1.5.

At a minimum, plans must develop scripts to respond to prospective and current enrollees for the situations listed below. Plan sponsors must submit to CMS only scripts noted with an asterisk (*) for review and approval; all others must be maintained by the plan sponsor.

- *Request for pre-enrollment information **
- *Request for post-enrollment information inquiries on:**
    - *Benefits**

- *Cost-sharing**
- *Formulary**
- *Network pharmacies, including whether a prospective enrollee's pharmacy is in the plan sponsor's network**
- *Provider networks, including whether a prospective enrollee's primary care physician is in the plan sponsor's network*
- *Out-of-network coverage**
- *Claims submission, processing and payment**
- *Formulary transition process**
- *How to access the Part D grievance, coverage determination (including exceptions) and appeals process**
- *How to obtain extra help*
- *Current TROOP status*
- *How to obtain needed forms*
- *How to replace a member identification card*
- *Service area*

NOTE: Telephone enrollment scripts are not considered "Informational Inbound Scripts" rather they are discussed *in §* 80.1.6.

80.1.4 - Requirements for Inbound Informational Scripts

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

Inbound informational scripts must be submitted for review and approval as an entire script, talking points, or bullet points. If scripts are submitted as talking or bullet points, the material must clearly delineate acceptable language and practices from prohibited language and practices.

Inbound information scripts must:

- *Include the purpose of the script in the heading (e.g. advertising, benefit information, post-enrollment information, or situational responses).*

- *Include the applicable Federal contracting statement. Plan sponsors must ensure that the language does not imply that they are endorsed by Medicare or are answering on behalf of Medicare.*

- *Include all required language contained in the Medicare Marketing Guidelines that is appropriate to the purpose of the script (e.g., all relevant disclaimers outlined in § 50).*

- *Include a privacy statement clarifying that the beneficiary is not required to give any information other than contact information to the CSR and that the information provided will not affect the beneficiary's ability to request enrollment or his/her membership in the plan.*

- *Use verbal responses to questions that follow the same guidelines required for similar printed materials in the same situation.*

- *Provide TTY numbers in conjunction with all other phone numbers.*

- *Clearly request the caller's consent when advocating follow-up calls. Use of phrases such as "would you like" or "may we" are acceptable. Phrases such as "we will" are not acceptable (refer to § 70.4 regarding unsolicited contact for more information).*

- *If applicable, any references to a VAIS benefit must use the appropriate disclaimer located in § 110.*

- *Always close by offering to send follow-up materials (published information) for inbound informational calls. Directing callers to the website is optional.*

- *Include a greeting that can be delivered by either a CSR or Interactive Voice Response (IVR).*
    - *Clearly state the plan name, the name of the programs being represented, and a brief description of the plan (e.g., an MA-PD plan, MA plan, section 1876 cost plan or PDP). If voice prompts are used for this purpose, all choices and access directions must be clearly stated. Options should include a re-play option and an opt-out to a CSR option. In addition, an after-hours voice mail prompt may be provided.*

    - *Provide options to access general information, enrollment information, or customer service. These options can be provided by either a CSR or an IVR. These options must be made available immediately after the plan name announcement. Under no circumstances can callers be connected directly to an enrollment specialist.*

- *Repeat the option that is selected by the caller (e.g., "Thank you for selecting general information" or "I can help you with general information"). If an IVR is used, opt-out options must be noted immediately after this announcement (e.g., "If this is not the information you want, press or say 1 to return to the main menu. Or, if you would like to speak to a customer service representative, press or say 4").*

NOTE: *Plan sponsors are not required to collect a beneficiary's medication and pharmacy information to calculate an estimated total annual cost for various plans during a customer service call.*

80.1.5 - Prohibited Activities For Inbound Informational Scripts

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

*Plan sponsors **are not** permitted to:*

- *Include information about other lines of business as part of the inbound script; however, scripts can ask if the caller would like to receive information about other lines of business offered by the plan sponsor.*

- *Transfer the caller to the enrollment area.*

- *Request prospective beneficiary identification numbers (e.g., Social Security number, bank account numbers, credit card number, HICN) as part of pre-enrollment inbound informational scripts (except information regarding the required special needs status when determining the appropriateness of enrollment in a SNP) or member specific scripts requesting a beneficiary's member ID number.*

80.1.6 - Requirements for Enrollment Scripts/Calls

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.60 (c), 423.32 (b)

Plan sponsors may accept enrollment requests via an incoming (inbound) telephone call to a plan sponsor's representative or agent (note that the guidance regarding inappropriate transfer of calls as noted in § 80.1.5 still applies). Telephone enrollment scripts and processes must follow the guidance provided in § 40.1.3 of Chapter 2 of the Medicare Managed Care Manual and § 30.1.3 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

Telephone enrollment scripts must be submitted in their entirety for review and approval. If scripts are submitted as talking or bullet points, the materials must clearly delineate acceptable language and practices from prohibited language and practices. In developing and submitting scripts for enrollment via inbound calls, plan sponsors must:

- *Clearly state the individual is requesting enrollment into [plan name] and the plan type.*

- *Comply with, at a minimum, all applicable requirements described in the CMS Eligibility and Enrollment Guidance in § 40.1.3 of Chapter 2 of the Medicare Managed Care Manual and § 30.1.3 of the Medicare Prescription Drug Benefit Manual.*

- *Although not part of the telephone enrollment request, plan sponsor may close the call with:*
    - *An offer to send or provide confirmation of having accepted the telephone enrollment request, such as a confirmation tracking number;*
    - *A summary of the plan into which the individual has requested enrollment;*
    - *A statement that the individual will receive a notice acknowledging the plan sponsor's receipt of the completed enrollment election or the plan sponsor's request for additional information;*
    - *Contact information for questions including toll-free telephone and TTY numbers.*

80.1.7 - Prohibited Activities for Enrollments Scripts/Calls

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.60 (c), 423.32 (b)

*Plan sponsors **are not** permitted to:*

- *Conduct outbound telephone enrollment except as required to perform outbound education and verification calls (refer to § 70.6)*
- *Transfer outbound calls to inbound lines for telephone enrollment;*
- *Market or enroll other lines of business as part of the telephone enrollment script; and*
- *Request or collect credit card numbers or bank account information for any purpose during the telephone enrollment call.*

80.1.8 - Requirements for Telephone Sales Scripts (Inbound or Outbound)

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 422.2264, 422.2268, 423.2262, 423.2264, 423.2268

Any telephone sales scripts (inbound or out-bound) must be submitted verbatim (talking or bullet points are unacceptable) however plans are asked/encouraged to include commonly asked questions in talking points or bullet points to CMS for review. Plan sponsors should incorporate all required disclaimers as provided in § 50, as well as all other relevant requirements as outlined in these Medicare Marketing Guidelines. For outbound scripts, plan sponsors must pay close attention to the guidance on marketing through unsolicited contacts in § 70.4 and 70.5 on specific telephone contact. This guidance extends to all downstream contractors.

Inbound calls made directly to a sales department or sales agent must clearly inform the beneficiary if/when the nature of the call moves from a sales presentation to telephonic enrollment. This must be done with the full and active concurrence of the Medicare beneficiary, ideally with a yes/ no question.

When conducting outbound sales calls:

- *Scripts must include a privacy statement clarifying that the beneficiary is not required to provide any information to the plan representative and that the information provided will in no way affect the determination of a beneficiary's eligibility for enrollment in the plan.*

- *Plan sponsors are prohibited from requesting beneficiary identification numbers (e.g. Social Security Numbers, bank account numbers, credit card numbers, HICNs) but in limited circumstances may inquire about an individual's special needs status to determine the appropriateness of enrollment in a SNP.*

80.1.9 - Requirements for All Other Inbound/Outbound Scripts

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 422.2264, 422.2268, 423.2262, 423.2264, 423.2268

The following guidance applies to all scripts that do not fall into the categories previously addressed (inbound informational calls, enrollment scripts, or inbound/outbound telephone sales calls).

- *Scripts must include a privacy statement clarifying that the beneficiary is not required to provide any information to the plan representative and that the information provided will in no way affect the beneficiary's membership in the plan. Outbound auto-dialings that are informational in nature will not be required to include this disclaimer in their scripts.*

- *Plan sponsors are prohibited from requesting beneficiary identification numbers (e.g. Social Security Numbers, bank account numbers, credit card numbers, HICNs). This policy does not extend to calls to existing members to conduct normal business related to enrollment in the plan (e.g., CTM complaint resolution). Note that in*

limited circumstances, plans may inquire about an individual's special needs status to determine the appropriateness of enrollment in a SNP.

- *Plan sponsors must say they are contracted with Medicare to provide prescription drug benefits or that they are a Medicare approved MA-PD plan, MA-only plan, section 1876 cost plan (with or without Part D benefits),, or PDP.*

- *Plan sponsors cannot use language in scripts that imply they are endorsed by Medicare, calling on behalf of Medicare, or that Medicare asked them to call the member.*

Plan sponsors must incorporate in their scripts all applicable disclaimers as noted in § 50, as well as all other relevant requirements outlined in these Medicare Marketing Guidelines (e.g., hours of operation, TTY number, etc.).

90 - Guidance on the Marketing Review Process

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Except where otherwise noted, all marketing materials must be reviewed prior to their use by the plan sponsor or any downstream organization that performs marketing activities on behalf of the plan sponsor. CMS' marketing review process is detailed in this section.

90.1 - Plan Sponsor Responsibilities

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

CMS reviews marketing materials to ensure that they are consistent with this chapter and are not materially inaccurate or misleading or otherwise make material misrepresentations of the plan sponsor or the products they offer. Generally, CMS does not review marketing materials for typographical or grammatical errors, unless such errors render the marketing materials inaccurate or misleading. *Plan sponsors are responsible for conducting a quality check prior to submitting all materials for review to CMS*. Generally, MA, MA-PD, and *section 1876* cost plan sponsors should not submit current contract year marketing materials for CMS review and approval after June 30th of that contract year. Note that this date does not apply to File & Use materials. In addition, all plan sponsors should be in compliance with CMS' record retention requirements, which require records to be kept for a period of ten years.

Prior to submitting materials as outlined below, plan sponsors are responsible for ensuring that materials are consistent with this chapter, and all other relevant CMS issued guidance and instructions. In addition, it is incumbent on the plan sponsor to create materials that provide

information in a manner that is clearly stated and in no way deceptive to the recipient. (Note that not all materials are read; some are scripts).

90.2 - Material Submission Process

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

Plan sponsors are required to submit materials for review through *the Marketing Module* of the HPMS. The HPMS Marketing Module is an automated tool that a plan sponsor uses to enter, track, and maintain marketing materials submitted to CMS for review and approval. HPMS can accept electronic *copies of plan sponsors'* actual marketing materials. The HPMS Marketing Module User Guide provides extensive information on how to use HPMS. However, plan sponsors must have a CMS plan issued User ID and password with HPMS access in order to log into the system. Plan sponsors will also need to associate their User ID with the contract *numbers with which they are associated in HPMS.*

90.2.1 - Mandatory Use of Marketing Material Review Checklists for All Documents

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

To ensure that the materials that are submitted to CMS and ultimately viewed by Medicare beneficiaries in making their health care coverage decisions meet the requirements as outlined in these *Medicare Marketing* Guidelines, plan sponsors must include applicable CMS checklists.

The checklist will require that a two-level review be performed by the plan sponsor prior to materials being uploaded into HPMS. Upon completion of the review, each of the two plan sponsor reviewers will attest that they have reviewed the document and that it meets the requirements as outlined by the checklist. The checklist will then accompany the material as part of the submission via a zip file.

CMS intends to create a standard checklist for plan sponsors to use when a checklist does not exist for a specific marketing material. Upon each checklist's release, plan sponsors will be required to use it, consistent with the instructions CMS will provide upon release. Checklists will be made available to plan sponsors on CMS web pages or via HPMS memoranda. While material-specific checklists will be tailored to the material that they represent, all checklists will contain the following minimum elements:

- Relevant requirements such as proper font size.
- All mandatory disclaimers.

- *A section acknowledging whether a material is a model document.*

- *A section citing the material's source (for example, an HPMS memorandum or a particular chapter of the Managed Care Manual or Prescription Drug Benefit Manual).*

CMS reviewers will utilize the same checklists as the basis for their review in order to ensure consistency.

90.2.2 - *Ad-Hoc Enrollee Communications Submission*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2260 (5)(vii), (6), 422.2262 (d), 423.2260 (5)(vii) ,(6), 423.2262(d)

In our efforts to streamline the review and approval of the beneficiary communications to current members, ad-hoc enrollee communications – as defined in § 20 – will not be considered marketing materials. However, CMS has the authority to review ad hoc enrollee communications, and, upon review, to determine that these communications may no longer be used. CMS has created an HPMS code [7013] for submission of ad hoc enrollee communications. These materials will be submitted File & Use. CMS reserves the right to retrospectively review such materials to ensure that the information being conveyed to enrollees is accurate and not misleading. Plan sponsors with concerns about whether a material fits the very narrow definition of an ad hoc enrollee communication should contact their Regional Office Account Managers or Marketing Reviewer.

90.3 - Material Disposition Definitions

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

For all marketing materials submitted for review by CMS, one of the following dispositions will be rendered - approved, disapproved, or deemed.

90.3.1 - Approved Disposition

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

If CMS approves a material submission, the material submission *has been determined to be* compliant with this chapter and any other applicable regulations, laws or relevant guidance. The

material submission is approved for use in the format in which it was submitted and may be distributed by a plan sponsor.

Marketing materials, once approved, remain approved until either the material is altered by the plan sponsor or conditions change such that the material is no longer accurate. However, CMS may at any time require a plan sponsor to change any previously approved marketing materials if found to be inaccurate, even if the original submission was accurate at the time of approval.

NOTE: *Prior to having an executed contract with CMS, plan sponsors' marketing material dispositions will be considered "conditionally" approved.*

90.3.2 - *Disapproved Disposition*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

If CMS disapproves a material submission, the material submission *has been determined to be* not compliant with *these Medicare Marketing Guidelines, or with* applicable regulations, laws or other relevant guidance. CMS will provide a specific reason for disapproval and provide an explanation for the disapproval generated by HPMS. CMS will provide citations to the requirement with which the material was found to be non-compliant.

90.3.3 - Deemed Disposition

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262(a)(ii), 423.2262(a)(ii), 422.2266, 423.2266

If CMS does not approve or disapprove marketing materials within the specified review time frame, the following will apply:

- Materials subject to a forty-five (45) day review period will be given the status of "Deemed Approved" on the forty-sixth (46th) day.
- Materials subject to a ten (10) day review period will be given a status of "Deemed Approved" on the eleventh (11th) day.
- *Plan sponsors that do not have a final contract will receive a conditional deemed approval. After the contract is awarded the materials disposition will be changed to "Deemed Approved" and can then be used.*

The status of "Deemed Approval" means that a plan sponsor may use the material. Plan sponsors should include [Deemed/MMDDYYYY] and follow the marketing material identification system described in § 40.1.

90.3.4 - Withdrawn Disposition

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

A plan sponsor can choose to withdraw a marketing submission prior to CMS acting upon that marketing submission (e.g., prior to beginning its review). However, plan sponsors cannot withdraw the marketing piece from HPMS; therefore, they should submit a written request to their CMS Regional Office Account Manager or Marketing Reviewer stating the reason(s) for the withdrawal. CMS is not able to initiate withdrawal of a marketing submission and is acting on behalf of the plan sponsor as specified in its written request.

90.3.5 - Additional Service Area (SA)/Low Income Subsidy (LIS) Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

All plan sponsors will be allowed to submit additional service area (SA)/LIS materials once the original material submission is complete. Users will be allowed to upload multiple additional *SA/LIS submission files for contracts and for PBPs***.** For example, when a plan has a service area that covers two States, one SB will be submitted as the original SB for one service area that covers one State. A plan sponsor can then submit another SB under the original SB submission which would cover the service area for the second State.

90.4 - Resubmitting Previously Disapproved Pieces

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

To expedite the review of previously disapproved pieces, plan sponsors should clearly indicate all changes/updates made to a material when it is resubmitted. Plan sponsors may meet this requirement by highlighting any text changes and/or inserting notes to altered areas on the material. Plan sponsors may develop an alternative process for identifying changes (e.g., bulleting all changes made within the comments section of HPMS when submitting the material) provided they discuss alternatives with and receive approval from the Account Manager.

Through this process, CMS expects that all areas changed from the first submission can be easily identified in the review process and reviewers can confidently complete reviews knowing plans have not altered the material in other ways. To that end, CMS recommends that when resubmitting a material, plan sponsors insert language in the comments section of HPMS attesting no other areas have been altered outside of the identified changes.

90.5 - Time Frames for Marketing Review

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262(a) 423.2262(a)

With the exception of those materials that qualify for File & Use (as outlined in § 90.6.*1), or the materials identified in § 90.2.2,* plan sponsors may not distribute or otherwise make available to eligible beneficiaries any marketing materials unless such materials have been submitted to CMS and *CMS has rendered a status of approved or deemed. The marketing review time period begins on the date of a marketing material's submission to HPMS.*

90.5.1 - 45-Day Standard Review Period

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262(a)(i), 423.2262(a)(i)

The default review period for materials is referred to as a standard review. A standard review provides CMS forty-five (45) calendar days in which to render a review decision. If, on the forty-sixth (46th) day, a decision has not been rendered by CMS the material will be considered "deemed approved."

The forty-five (45) day review period applies each time an individual marketing material is submitted to CMS for review. For example, if a material is submitted to CMS for review and on the thirty-second (32nd) day CMS renders the decision of disapproved, upon correcting the material's deficiencies and resubmitting the piece, the forty-five (45) day clock starts anew.

The forty-five (45) day standard review applies to materials submitted where:

- No standardized or model language is available
- Model language is available and the plan sponsor has chosen to make modifications to the model language.
- *An SB that includes a Section III.*

90.5.2 - 10-Day Model Review Period

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262(a)(i), 423.2262(a)(i)

When a plan sponsor follows CMS model language without modification, CMS must render a decision within ten (10) calendar days. If, on the eleventh (11th) day, a decision has not been rendered by CMS the material will be considered "deemed approved." As with the standard review period, when a material is resubmitted for a ten (10) day review, *CMS is provided with a new ten (10) day review period to render its decision.*

The ten (10) day review period only applies when the plan sponsor has followed the CMS model without modification. "Without modification" means the plan sponsor used CMS model language verbatim except where indicated and allowed by CMS (for example variable fields). (*NOTE: The "without modification" exception will be allowed for grammatical errors only (e.g., if the model has grammatical errors then the plan sponsor may correct the model's grammatical errors.)* It also means that the plan sponsor has followed the same sequence as provided in the model. See § 90.7.3 for additional information on model materials. *To facilitate reviews, plan sponsors should indicate the model/exhibit title and applicable CMS chapter /manual or HPMS memoranda date within the comments section of HPMS.*

Plan sponsors must indicate that a marketing material qualifies for model review when that material is uploaded into HPMS. This feature will only be present when a model document exists. It is likewise incumbent on the plan *sponsor* to ensure that any model that has been modified in any way is not submitted for a model review. Materials that are found to be non-model yet are uploaded for model review will be disapproved. A continued submission of non-model materials as model will be viewed as a compliance issue.

90.6 - File & Use Program Overview

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262(b), 423.2262(b)

Plan sponsors have the ability to utilize the File& Use program. To do so, plan sponsors must submit the File & Use certification form to the respective CMS Account Manager. Materials that qualify under the File & Use process can be distributed five calendar days after submission to CMS, but no earlier than any date established by CMS for use of specific document/materials. All plan sponsors can use the File & Use process for selected marketing materials as defined by CMS. Plan sponsors using the File & Use process must submit File & Use eligible marketing materials to CMS five calendar days prior to distribution and certify that the materials comply with this chapter.

90.6.1 - Materials Qualified for the File & Use Submission

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262(b), 423.2262(b)

The *following* materials are qualified for the File & Use *provided they are used without modifications and the plan sponsor has submitted a File & Use certification to CMS*:

- Provider directory (including combined provider directory and *pharmacy* directory),
- *Standardized combined ANOC/EOC*
- Pharmacy directories;
- *Abridged and comprehensive formularies*;
- Certain CMS enrollment/disenrollment letters; and
- Certain claims, grievance, organization/coverage determinations (including exceptions), and appeals model letters.
- *OMB-approved forms (although plan sponsors may add the material ID as specified in § 40.1.*

File & Use submissions for direct mail and general advertising materials may be allowed provided the materials are not explanatory marketing materials that mention benefit and plan premium information as stated in § 50.1.4.

Materials that are not eligible for File & Use submission are direct mail and general advertising materials that are explanatory marketing materials that mention benefit and plan premium information as described in § 50.1.4.

The HPMS Marketing Module identifies those materials that qualify for File & Use under the material code look-up functionality.

***NOTE**: If a plan sponsor (s) does not have File & Use certification they are considered ineligible to submit documents as File & Use. In this instance, any such submissions would be subject to compliance actions.*

90.6.2 - Materials Not Qualified for File & Use Submission

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262(b), 423.2262(b)

Materials that do not qualify for File & Use are those that pose greater risk to a Medicare beneficiary if they are inaccurate in any way. These documents include but are not limited to:

- SB;
- Member Handbook;

- Member ID card;
- Enrollment forms;
- Disenrollment forms, and
- Errata sheets for *incorrect* SBs, ANOC/EOCs or LIS riders
- *Any template materials*

In addition, *explanatory marketing materials as defined in § 50.1.4, unless expressly identified by CMS as qualified for the File & Use processes, must be submitted for either a forty-five (45) or ten (10) day review process as provided in HPMS*.

90.6.3 - Restriction on the Manual Review of File & Use Eligible Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262(b), 423.2262(b)

Plan sponsors that choose to utilize File & Use must submit at least ninety (90) percent of *marketing* materials that qualify for File & Use under this process. *More specifically, p*lan sponsors choosing to utilize File & Use *should request a manual review of no more than ten (10) percent of materials that qualify for File & Use (including, but not limited to model materials that qualify for File & Use submission).* If CMS determines that a sponsor *falls below the ninety (90) percent threshold for a given month (reports will be run by CMS at the end of each month reflecting the cumulative compliance for the contract year thus far), the organization will be so advised by the Marketing Reviewer and/or Account Manager and urged to bring their ratios into compliance with this provision. Upon receiving two of these advisements within a given contract year, CMS will require that all materials submitted by the plan that qualify as File & Use be submitted as such until the number of materials submitted meets the 90/10 threshold. If an organization fails to comply after CMS has taken aforementioned steps, additional compliance actions may be taken.*

All materials must include a marketing material identification number as outlined in § 40.1

90.6.4 - Loss of File & Use Certification Privileges

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262(b), 423.2262(b)

A plan sponsor may lose File & Use Certification status if it:

- Uses materials that do not meet the requirements of this chapter;

- Fails to file two or more materials at least five (5) calendar days prior to distribution or publication; or

- *Is found after a targeted review by CMS, to consistently submit a large number of File & Use materials through a forty-five (45) day review process, or to consistently submit through the File & Use process materials that do not meet the requirements of these Medicare Marketing Guidelines.*

If CMS revokes a plan sponsor's File & Use Certification privileges, the plan sponsor may be reinstated under File & Use Certification after at least six months have passed since its privileges were taken away. If a plan sponsor loses its File & Use Certification privileges twice, it may not be reinstated under File & Use Certification until at least one year has passed since the date the privileges were taken away the second time.

Following are the certification procedures for Part D sponsors:

- Unless the PDP sponsor requests a waiver from the File & Use Certification process, all PDP sponsors must submit File & Use Certification marketing materials to CMS five (5) calendar days prior to distribution and certify that the materials comply with this chapter. It is important to note that CMS will verify that the marketing materials submitted by the organization qualify for the File & Use Certification process.

- The PDP sponsor may submit File & Use Certification materials prior to executing a contract with CMS. The CMS contract will contain a provision by which the PDP sponsor will certify that the material submitted prior to the execution of the contract, as well as all File & Use Certification materials submitted subsequent to the execution, are accurate, truthful, not misleading, and consistent with CMS requirements. Thus, by executing the CMS contract, the appropriate officer of the PDP sponsor is attesting to his/her PDP's compliance with the File & Use Certification requirements.

- As each marketing material is submitted, the PDP sponsor must attest to the completeness and accuracy of the material through an electronic attestation. The electronic attestation does not have to be completed by the same person who signed the original contract.

Following are the certification procedures for MA, MA-PD, and section 1876 Cost Plans:

- *Each plan sponsor should submit the File & Use Certification marketing materials to CMS at least five (5) calendar days prior to distribution and certify by the plan sponsor's CEO/CFO or designee that the materials are in compliance with CMS requirements. As each item of marketing material is submitted, each plan sponsor is responsible for ensuring the accuracy and completeness of its marketing materials and adhering to CMS requirements. All certification forms must be sent to CMS (refer to Model File & Use Certification form, Appendix 4). The requirement for submission of a signed certification form is a one-time only requirement, and the signed certification is effective until further notice. A completed and signed certification form must be received from the plan sponsor before it may submit File & Use certification materials. The plan sponsor should mail the signed certification to its appropriate CMS Regional Office. The File & Use certification*

form (see Appendix 4) states that the plan sponsor agrees that all advertising materials and model documents that are used are accurate, truthful and not misleading.

- CMS will verify that the marketing materials submitted under the File & Use Certification process meet the following administrative requirements: 1) CMS has received a signed certification form from the plan sponsor's CEO/CFO or designee; 2) materials submitted qualify for the File & Use Certification process; 3) a completed transmittal form is attached to the materials (unless they are electronically submitted through HPMS); and 4) all materials include the plan ***sponsor's*** contract number (***e.g.,*** H####, R####, S#### *or MCE identifier of Y####*) as a prefix to the marketing materials identification number.

90.7 - Additional Guidance for CMS Provided Language/Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

The following sections address CMS requirements when CMS issues documents and/or language to be used as instructed.

90.7.1 - Standardized Language

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262 (c), 423.2262 (c)

Standardized language refers to language developed by CMS or other Federal agencies (e.g., Office of Management and Budget (OMB) approved forms) which is mandatory for use by plan sponsors and cannot be modified. Impermissible modifications include altering the content, format, or language in any way. For OMB-approved forms submitted as File & Use refer to § 90.6.1.

90.7.2 - Required Use of Standardized Model Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262 (c) , 423.2262 (c)

Standardized model materials are model documents that a plan must utilize without modification. In instances where CMS provides a standardized model document, plan sponsors must use the document without altering the text or its order. Unless otherwise directed, the only allowable alterations to standardized models include populating variable fields, correcting

grammatical errors, adding the plan name/logo and adding the CMS marketing material identification number.

We clarify that standardized models differ from non-standardized model materials in that standardized models are mandatory for use by plan sponsors as written. Conversely, plan sponsors may or may not use non-standardized model documents (see § 90.7.3). When utilizing a standard model material, plan sponsors must remove any reference to the words "exhibit", "model", or "appendix" contained within the title of the model document (note that the title of the standardized model should remain). For CY2011, standardized model materials that are mandatory for use by plans include:

- *Summary of Benefits*
- *Annual Notice of Change/Evidence of Coverage*

90.7.3 - Model Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262 (c), 423.2262 (c)

For certain materials, CMS has developed model documents that are available for use by the plan sponsor. The use of CMS model documents is optional unless otherwise directed by CMS or if the material falls into the category of standardized model materials (refer to § 90.7.2). Generally, model documents used without modification will result in a ten (10) day marketing review period. Model documents modified by the plan sponsor will result in a forty-five (45) day review period.

The following modifications to CMS model materials will still render the material allowable for use under the ten (10) day review period; populating variable fields, correcting grammatical errors, adding the plan name/logo, and adding the CMS marketing material identification number. Unless otherwise required, plans may choose to retain the title of the model document or modify the title to make it more beneficiary friendly. Note that any reference to the words "exhibit,""model," or "appendix" contained within the title of the model document must be removed. Any other modifications made to the document will make the material subject to the standard forty-five (45) day review process and/or ineligible for File & Use submission.

It is important to note that materials found to be non-model yet uploaded by the plans sponsors for model review will be disapproved. Further continued submission of non-model materials as models or submission of models inappropriately coded as used without modification will be viewed as a compliance issue.

To facilitate reviews, plan sponsors should indicate the model/exhibit title and applicable CMS chapter/manual or HPMS memorandum date within the comments section of HPMS whenever a model document is submitted. If the document is an attachment to a CMS issued memorandum,

the plan sponsor should individuate the subject and the date CMS issued the HPMS memorandum.

CMS expects that the final versions of a model document will be submitted. Any models submitted with brackets and variable fields should be submitted via the template process (see § 90.10). Models submitted with variable fields that are not submitted as templates will be disapproved.

90.8 - Template Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

A "template material" is any marketing material that includes placeholders for variable data to be populated at a later time by the plan sponsor. Variable elements can be specific to one plan or can apply to multiple plans within the same plan sponsor that utilize the same base materials. Utilizing template materials allows a plan sponsor to submit one "master document" rather than having to submit a new document every time the variable data is changed. Examples of variable elements include date and location information for sales presentations, benefits that may vary between plans, cost sharing, premium and plan sponsor names.

90.9 - Submission for Summary of Benefits Submitted as a Template Prior to Bid Approval

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

To ensure plan sponsors are able to submit information efficiently and with minimal burden, CMS allows plan sponsors to create and submit an SB prior to bid approval. Should plan sponsors choose to exercise this option, they may submit an SB with variable placeholders around plan benefits and cost-sharing information. These materials should be submitted as templates and populated after bid approval. These populated materials will not need to be resubmitted to the appropriate CMS Regional Office for additional approval prior to use, but plan sponsors must submit each variation of the template through HPMS as a populated template within thirty (30) days of populating the materials. If any changes or corrections to the bid occur after the template is approved, the plan sponsor is responsible for correcting all materials to reflect the changes.

If a plan sponsor chooses to submit a SB for review with no section III, no comprehensive written statement of benefits (section IV), and no hard copy changes, it will be treated as a standardized document and reviewed using the ten (10) day timeframe. However, if the plan sponsor chooses to submit the SB with section III and/or section IV it will be reviewed within the forty-five (45) day time period. Model documents used as templates may not be modified.

Plan sponsors should not be submitting SBs with variable placeholders around plan benefits and cost-sharing after bids have been approved; rather, these SBs should be submitted as final documents. The SB is the only document that qualifies for an expedited review.

90.10 - Submission of Templates for All Material Types

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

Template material or model template materials must be uploaded to CMS through the HPMS marketing module and they must show how the placeholders will be populated by inserting the name of the field within greater than and less than signs (e.g., <date>), or populate the placeholder fields with all variables within the greater than and less than signs (e.g., <$10.00 Copay/$15.00 Copay>). Template materials will have only one marketing identification number regardless of the number and combination of variable elements. Changes to non-variable text in the template must be submitted for review and approval by CMS.

CMS will review the templates and will render a review decision within ten (10) or forty-five (45) days depending on the material's type and whether the plan sponsor has submitted model or non-model language.

Changes to the *non-variable* text in the templates once approved will require additional submission, review, and approval by CMS. Changes to placeholders populated by date or location, phone numbers, addresses, and other non-benefit or non-premium information are not required to be submitted as new material. Likewise, co-branding information added to previously approved template materials is not subject to an additional review, as long as the changes are limited to populating existing variable fields (e.g., organization name, logos or contact information).

Plan sponsors must submit the final template material that has been populated (in the placeholders) with plan specific information. The material need not be approved again by CMS prior to use, but plan sponsors must submit the materials through HPMS within thirty (30) days under the applicable "Final Expedited Review / Populated Template" material code. If there are any changes or corrections to materials (for example, the benefit or cost-sharing information differs from that in the approved bid) *the plan sponsor* will be required to correct those materials for prospective members and send errata sheets/addenda/reprints to current members by a reasonable timeframe. In cases where non-compliance is discovered, the plan sponsor may be subject to penalties including intermediate sanctions and civil money penalties.

NOTE: Identical materials submitted separately and not noted as template materials are subject to separate reviews.

90.11 - Submission of Non-English (*Alternate Formats) Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264 (e), 423.2264(e)

CMS requires that plan sponsors make marketing materials available in any language that is the primary language of more than ten percent of a plan's PBP service area**.** *In addition, enrollee information (as identified in § 30.10) must be made available to the visually impaired upon request.*

"*Alternate Formats" materials must be based on previously approved English versions of the same material. As such, the plan *sponsor* must submit an English version for approval first.

Upon approval of the English version, the plan sponsor must submit the following:

- The non-English version of the marketing piece (**NOTE**: "*Alternate Formats" materials that cannot be submitted via HPMS, e.g., Braille, should be kept on file at the plan.)

- A letter of attestation that must be signed and certified by an authorized official employed by the plan sponsor, and must attest that the translation conveys the same information and level of detail as the corresponding English version.

Plan sponsors that submit Non-English (*Alternate Formats) materials must designate the material as "*Alternate Formats" in HPMS using the following process during data entry:

1. The material must be given a unique Material ID.

2. *The user must select YES in the "*Alternate Formats" field.*

3. Upon selecting YES in the "*Alternate Formats" field, the user will be required to enter the Material ID of the original English version in the "*Alternate Formats Original Material ID:" field. (**NOTE**: this field will only display if the "*Alternate Formats" field has YES selected.)

4. The submitted "*Alternate Formats" material will receive a Material Status of "Alternate Formats".

The designation of "*Alternate Formats" will inform the Regional Office reviewer that there are non-English versions submitted. If the plan sponsor decides to submit additional "*Alternate Formats" materials with its attestations at a later date, it may use the same process described above for each new material, as needed. Please note that any changes or revisions that are made to the English version should be accurately reflected in non-English materials and re-uploaded as required.

All plan sponsors will be subject to verification monitoring review and associated penalties for violation of CMS policy. In addition to verifying the accuracy of non-English marketing materials through monitoring review, CMS will also periodically conduct marketing review of non-English materials on an "as needed" basis. If materials are found to be inaccurate or do not convey the same information as the English version, plan sponsors may not continue to distribute materials until revised materials have been approved.

*All sponsors will be allowed to submit "*Alternate Format materials" once the original English version of the material submission is complete. In general, for marketing with materials that contain non-English or Braille information (in whole or in part), the plan sponsor must submit the non-English(except for Braille materials which must be kept on file at the plan) of the marketing piece, an English translation of the piece, and a letter of attestation. Users will be allowed to upload multiple alternate format files for contracts and for plan benefit packages. If a plan sponsor allows online enrollment through the plan sponsor's secure website, the online enrollment mechanism does not need to be available in "*Alternate Format" materials. However, in addition to other requirements (refer to § 100 for details), the online enrollment mechanism must indicate that "Alternate Format" materials are available by contacting the plan sponsor directly.*

90.12 - Acceptable Formats

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

Plan sponsors must use HPMS to enter all pertinent information related to a material submission and attach the material in electronic format to this entry. When submitting material, include within the comments field on the Marketing Materials Transmittal screen, the plan number and PBP for which materials are being submitted. The following are acceptable electronic formats for submitting these materials:

- Zip Files (.ZIP)
- Portable Document Format (.PDF)
- Microsoft Word (.DOC/DOCX)
- Joint Photographic Experts Group (.JPG)
- Microsoft Excel (.XLS/ .XLSX)
- DOS Text (.TXT)
- Graphics Interchange Format (.GIF)
- WordPerfect (.WPD)

Other formats may be acceptable but must be agreed upon by the plan sponsor's Account Manager prior to making the submission.

90.13 - Submissions Outside of HPMS

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

Under extraordinary circumstances, and with prior concurrence of CMS, marketing materials may be submitted directly to CMS by mail, express mail, fax, or some other method. Please note that if materials are submitted to CMS outside of HPMS the review period begins when CMS is in possession of the materials.

90.14 - Requirements for Joint Enterprise for PDPs and Regional Preferred Provider Organizations (RPPOs)

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

Joint enterprises are expected to:

- Market the plan under a single name throughout a region; and
- Provide uniform benefits, formulary, enrollee customer service, grievance, coverage determination, and appeal rights throughout the region.

Marketing materials for the joint enterprise may only be distributed where one or more of the contracted plan sponsors creating the single entity is licensed by that State as a risk-bearing entity or qualifies for a waiver under 42 CFR 423.410 or 42 CFR 422.372. All marketing materials must be submitted under the joint enterprise's contract number and must follow CMS requirements.

90.15 - Multi-Contract Entities (MCEs)

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

If a plan sponsor operates in the jurisdiction of more than one of the CMS Regional Offices, marketing materials should be submitted to the appropriate reviewer in the lead region (e.g., the region where the plan sponsor's Account Manager is located). Multi***re***gion plan sponsors that

submit template materials are not required to send approved copies of the template to local regions, since this information is already available within HPMS.

90.16 - Review of Materials in the Marketplace

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2268, 423.2268

To ensure compliance with this chapter, CMS periodically conducts reviews of plan sponsor materials. Reviews could include, but are not limited to, the following activities:

- Review of on-site marketing facilities, products and activities during regularly scheduled contract compliance monitoring visits.
- Random review of actual marketing pieces as they are used in/by the media.
- "For-cause" review of materials and activities when complaints are made by any source, and CMS determines it is appropriate to investigate.
- "Secret shopper" activities where CMS requests plan sponsor materials such as enrollment packets.

If a plan sponsor's materials are found to be non-compliant, CMS may enforce various compliance actions. Additionally, plan sponsors may be required to prepare an addendum or reissue the materials at no expense to the Government.

90.17 - File & Use Retrospective Monitoring Reviews

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262(b), 422.2264, 423.2262(b), 422.2264

CMS will periodically conduct retrospective reviews of materials that were submitted under File & Use to ensure compliance by those plans that utilize this feature. Failing to abide by the File & Use Certification requirements may result in corrective action against the plan sponsor to protect the interest of Medicare enrollees. Plan sponsors submitting marketing materials under the File & Use Certification process through HPMS will be reminded, on an ongoing basis, of their responsibility to adhere to CMS requirements and to submit an *electronic attestation at the time a material is submitted.*

90.17.1 - Template Materials Quality Review and Reporting of Errors

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

CMS may also conduct retrospective reviews, quality checks, or audits of populated templates. CMS also expects that plan sponsors will perform quality reviews and testing as necessary to ensure that the means of populating and distributing templates with information from the approved bid is accurate. When errors are discovered, a plan sponsor must report them to its Account Manager. In addition, plan sponsors may be required to remedy the error by providing beneficiaries with updated information via errata sheets or addenda. Note that any materials, such as errata sheet or addenda, must be reviewed and approved by CMS prior to their use.

90.18 - Specific Guidance on the Submission of Websites for Review

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

Given that Internet use has increased among Medicare beneficiaries as a vehicle for accessing information, it is vital that information provided online allows beneficiaries to make an informed decision about their medical and prescription drug coverage. Therefore, plan sponsors must submit all MA and PDP websites for review. Plan sponsors should submit their websites via links in a Word document for a *forty-five (45) day* review through HPMS under category code 4006-Internet web pages. *Once a plan sponsor's website is reviewed and approved in entirety, a plan sponsor may update specific pages of this same website by submitting only the pages to be changed using the same submission process as described above (submit a link in a Word document for a forty-five (45) day review). Plan sponsors are reminded that websites are required to meet all CMS guidelines, 508 compliance requirements, and all guidance noted in § 100. Plan sponsors should submit any previously approved websites links for review if there are any changes or updates related to Medicare information.*

Plan sponsors may make the website available for public use during the CMS review period; however plan sponsors must include the disclaimer "Pending CMS Approval" on their website until CMS has granted final approval. Use of the website while under CMS review applies only to the website text and not documents contained on the website (for example a plan may not post an unapproved member handbook on the website).

Renewing plan sponsors must have website content available to Medicare beneficiaries beginning October 1 for the next contract year. Plan sponsors must maintain current contract year content on their website at least until December 31st. In addition, each year's content must

be in a separate and distinct area on the plan sponsor's website for ease of beneficiary navigation (for example having a splash page that allows the viewer to select information *for the current plan year and/or subsequent plan year).*

90.19 - Special Guidance on the Submission of the SB and ANOC/EOC

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

HPMS now restricts multiple submissions of the SB and ANOC/EOC for the same contract number and plan ID (PBP number). This requirement was implemented to ensure that CMS has the ability to capture the final plan version of each ANOC/EOC and SB in HPMS. Therefore, if a plan sponsor attempts to upload an SB or ANOC/EOC when the same document type has been previously submitted for review under a specific contract number and plan ID, the plan designation check boxes will be disabled. In order to submit the new replacement or additional SB or ANOC/EOC, plans must contact the Regional Office and have the previously submitted material "Disapproved" or "Withdrawn" (which results in a new review period). Plan sponsors that have multiple versions of the SB and ANOC/EOC for one plan ID may submit those versions in a Zip file.

One of the impacts of this requirement is in the submission of non-English versions of the SB and ANOC/EOC. In the past, non-English versions were submitted under separate material IDs. Plan sponsors that submit non-English versions must submit the materials under one material ID. The material should be designated as having "Alternate Formats" by choosing the "Yes" option on the "New Material" screen. After designating the plans covered by this material, the user should upload a zip file containing all versions of the SB and ANOC/EOC.

90.20 - Specific Guidance on the Submission of General Advertising Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

Direct mail and advertising materials may be submitted as File & Use provided the materials are not explanatory marketing materials that contain benefit and plan premium information as detailed in § 50.1.4. Direct mail and general advertising materials that are explanatory marketing materials that contain benefit and plan premium information as described in § 50.1.4 will not be eligible for File & Use.

90.21 - Materials Not Subject To Review

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2260, 422.2262, 423.2260, 423.2262

The following items are examples of materials that are not subject to review by CMS and hence should not be uploaded into HPMS. While the materials listed below are not subject to CMS review, plan sponsors are still responsible for ensuring that all materials intended for Medicare *beneficiaries meet all the applicable requirements* in these *Medicare Marketing G*uidelines. In addition, plan sponsors should have a means of tracking and maintaining such materials so as to have them available upon request by CMS.

- Privacy notices (privacy notices, however, are subject to enforcement by the Office of Civil Rights)
- Press releases *that do not include any plan-specific information (e.g., information about benefits, premiums, co-pays, deductible, benefits, how to enroll, networks)*
- Certain member newsletters (newsletters are not subject to review as marketing materials unless sections are used to enroll, disenroll, and communicate with members on product specific information (e.g., benefits or coverage), membership operational policies, rules and/or procedures)
- Blank letterhead/fax coversheet that do not include promotional language
- General health promotion materials that do not *include* any specific plan related information. (e.g., health education and disease management materials). In general health promotion materials should meet CMS' definition of "educational."
- *Non-Medicare beneficiary-specific materials that do not involve an explanation or discussion of Part D, MA, or section 1876 cost plans (e.g., notice of check return for insufficient funds, letter stating Medicare ID number provided was incorrect, billing statements/invoices, sales, and premium payment coupon book)*
- Sales representative recruitment and training documents
- Customer service correspondence pertaining to unique questions or issues that affect an individual or small subset of the plan's enrollment

- Medication Therapy Management (MTM) program material that address issues that are unique to individual members
- Materials used in the education of beneficiaries and other interested parties. The materials must meet the definition of "educational." See § 70.7 for more information on educational material
- Coordination of Benefits *notifications (as provided in § 50.2 of Chapter 14 of the Medicare Prescription Drug Benefit Manual)*
- *Health Risk Assessments*
- Mail order pharmacy election forms
- Other member surveys
- VAIS (refer to § 110)

90.22 - Submission of Multi Plan Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

CMS will issue guidance on a multi-plan material submission process late in 2010.

100 - Special Guidance on Plan Sponsor Websites

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

(Section 508 of the Rehabilitation Act (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 (P.L. 105-220), August 7, 1998)

All plan sponsors are required to have an Internet website that is compliant with web-based technology and information standards for people with disabilities as specified in section 508 of the Rehabilitation Act. For additional information, please go to the following website address: http://www.section508.gov.

100.1 - Plan Sponsor Website Requirements

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264(a), 423.2264(a)

All plan sponsors, *including section 1876 cost plans,* must have a website or web page dedicated to each product they offer (with the exception of employer based plans; refer to § 130). This website/page must include the name of the plan sponsor and clearly indicate that it is a Medicare contractor (See § 50 regarding marketing material types and applicable disclaimers). All marketing materials that include a web address for the sponsor's website should link directly to the organization's Medicare specific pages.

A plan sponsor may provide access to its organization's other lines of business on its Medicare-based website. However, to avoid beneficiary confusion, any links provided by the plan sponsor to health-related or non-health related products/services must be clearly labeled as such to allow the beneficiary to make an informed decision and understand that by clicking on those links, he/she will be leaving the Medicare-specific web pages. Plan sponsors should reference § 170 to ensure compliance regarding the use of beneficiary information requirements. In addition, any formulary information placed on websites must comply with § 60.5.4 in addition to § 100 of the guidance.

Plan sponsors are allowed to utilize social networking websites (e.g., Facebook, Twitter) to promote their plan to Medicare beneficiaries. However CMS intends to monitor the use of such social networking site for this purpose in order to ensure that plan sponsors do not mislead Medicare beneficiaries. If warranted, we will issue additional guidance limiting as appropriate plan sponsors' use of social networking websites to market their Medicare products. Plan sponsors must submit advertisements that will be utilized for Facebook or Twitter for review and approval.

Any marketing materials that a plan sponsor places on its website must be in a minimum twelve (12) point Times New Roman-equivalent font. CMS acknowledges that the plan sponsors do not have control over the actual screen size shown on individuals' computer screens that can be adjusted by the user. Therefore, the twelve (12) point font requirement refers to how the plan sponsor codes the font for the web page, not how it actually looks on the user's screen.

100.2 - Organization Website Content

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

Website content should use language from marketing materials that have been reviewed and approved and/or appropriately submitted to CMS under File & Use, in accordance with this chapter (e.g., advertising, SB, formulary, pharmacy/provider directory, and EOC). Plan sponsors may provide this information via links from Web pages; however, the navigational icons used to access these links must clearly describe the information contained on each informational link. Links can consist of numerous pages as long as the navigational icons used within the linked pages clearly describe the information being accessed. *For specific guidance on submission of website reviews refer to § 90.18.*

Plan sponsors must provide certain current contract year information on a website for members and prospective enrollees. Renewing plan sponsors are also required to provide website content beginning October 1 for the next contract year. Plan sponsors must maintain current contract year content on their website until at least December 31. In addition, documents and information related to upcoming contract year content must be clearly distinguished from current contract year documents and information. Beneficiaries should be able to quickly identify which year's information they are reviewing (e.g., 2011 Summary of Benefits and 2010 Summary of Benefits). The website content for the upcoming contracting year must be submitted to CMS as described in § 90.18 and contains all information in Appendix 3.

Plan sponsors are required to include the approved material ID on their Medicare website. For example:

- Pharmacy directory SXXXX_XX *CMS*Approved *MMDDYYYY*.

The following information must be included on all plan sponsor websites:

- Toll-free customer service number, TTY number, physical or Post Office Box address, and hours of operation.
- Plan Description (for each product offered by the plan sponsor):
    - Service area(s)
    - Benefits
    - Applicable conditions and limitations
    - Premiums
    - Cost sharing (e.g., co-payments, co-insurance and deductibles)
- Any conditions associated with receipt or use of benefits
- When applicable, provide the notice associated with removing a Part D drug from the Part D plan's formulary, adding prior authorization, quantity limits, step therapy or other restrictions on a drug and moving a drug to a higher cost-sharing tier. This information is to be maintained on the website until the next annual mailing of the updated formulary.
- Process for contacting Social Security Office or Medicaid to inquire about LIS status or level.

100.2.1 - *Pharmacy Access Information*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.120(a) (1), 423.128(b) (5), (7), (9)

All plan sponsors that offer Part D benefits must include the following on their website;

- Pharmacy information as defined above in § 60 *– 60.5.7.*
- Number of pharmacies in network.
- How the plan meets access requirements (e.g., <Plan Name> has contracts with pharmacies that equal or exceed CMS requirements for pharmacy access in your area).
- Description of out-of-network coverage.
- Current formulary information (updated monthly) based on guidance provided in § 60.5.4.
- *Drug utilization management information that is easy to understand, clearly marked and easy to find.*
- *Information on the plan transition process.*
- An explanation of the plan's Part D grievance, coverage determination (including exceptions), and appeals processes, and the procedures plan members must follow to file a grievance or request a coverage determination (including an exception) or appeal.
- Quality assurance policies and procedures, including Medication Therapy Management (MTM), and drug and/or utilization management. Plan sponsors must identify the conditions for which MTM programs are available, inform beneficiaries that these programs may have limited eligibility criteria, make clear that these programs are not considered a benefit, and remind beneficiaries to contact the organization's customer service for additional information.
- Potential for contract termination.
- Beneficiaries' and plan's rights and responsibilities upon disenrollment.
- How to obtain an aggregate number of grievances, appeals, and exceptions filed with the plan sponsor.
- Process for contacting Social Security Office or Medicaid to inquire about LIS status or level.

100.2.2 - *Provider Access information*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111(b) (3)

MA, *MA-PD*, and *section 1876* cost plans must include an electronic provider directory applicable for all products and defined by service areas or general geographic area. This may be accomplished by:

- Posting a searchable "master" provider directory that represents the aggregate network for the plan sponsor.

- Posting individual provider directories by product and/or service area (e.g., mirroring those that will be printed for the plan sponsor's membership).

100.2.3 - Specific Guidance Regarding Grievance, Coverage Determination (including Exceptions) and Appeals Website Requirements

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111(b) (8), 423.128(b) (7)

Plan sponsors must include the following specific information on the organization's website:

- A summary of the plan sponsor's grievance, coverage determination (including exceptions), and appeals processes.

- Instructions for requesting a coverage determination (including an exception), including:

    - The telephone number designated for receiving oral requests (plan sponsors must accept *standard and* expedited requests *for benefits* verbally, and may choose to accept standard requests *for payment* verbally).

    - The mailing address and fax number designated for receiving written requests.

- Instructions for requesting a redetermination (appeal), including:

    - The telephone number designated for receiving oral requests (plan sponsors must accept expedited requests verbally and may choose to accept standard requests verbally).

    - The mailing address and fax number designated for receiving written requests.

- A link to the plan sponsor's redetermination request form, if the plan has developed one.

- Any form developed by the plan sponsor to be used by a physician or enrollee to satisfy a prior authorization or other utilization management requirement.

- Any form developed to be used by physicians when providing a supporting statement for an exceptions request.

- Contact numbers that enrollees and physicians can use for process or status questions.

- Instructions about how to appoint a representative and a link to CMS' Appointment of Representation form (Form CMS-1696) located on CMS' Part D appeals webpage: http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/13_Forms.asp.

- A link to the plan's Evidence of Coverage (EOC) and a reference to the sections on the EOC that discuss the grievance, coverage determination (including exceptions), and appeals processes.

- A link to the Request for Medicare Prescription Drug Determination Request Form (for use by enrollees) located on CMS' Part D appeals webpage: http://www.cms.hhs.gov/PrescriptionDrugApplGriev/13_Forms.asp.

- A link to the Medicare Part D Coverage Determination Request Form (for use by provider) located on CMS' Part D appeals webpage: http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/13_Forms.asp.

100.2.4 - *Low Income Subsidy (LIS) Website Premium Summary Table for People Receiving Extra Help*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 423.128(b) (2) (ii) and (iii)

Plan sponsors must inform potential enrollees of what their plan premium will be once they are eligible and receive the LIS. *For territories, this information does not need to be included. Plan sponsors should use the model LIS Premium Summary Table to ensure that the following information is available for each plan benefit package (PBP) they offer:*

- A statement indicating that the enrollee's premium will generally be lower once he/she receives extra help from Medicare

- The four different premium amounts

- An explanation that the premiums listed do not include any Part B premium the member may have to pay, and

- A statement indicating that the premiums listed are for both medical services and prescription drug benefits (MA-PD plans only)

NOTE: Even if plan sponsors offer a $0 plan premium they should still include the above information on their website.

100.3 - Required Links

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.111(b) (8), 422.2264(a), 423.128(b) (7), and 423.2264(a)

The following information must be accessible via a link on the plan sponsor's website. If the specific marketing materials have not been reviewed and approved or appropriately submitted to CMS under File & Use in accordance with this chapter, an inactive link must be included on the website with a notation (e.g., coming soon).

- SB
- Enrollment instructions and forms
- EOC
- LIS Premium Summary Chart
- Privacy Notice (privacy notices are subject to enforcement by the Office of Civil Rights)
- *Ensure that plan sponsor includes a link to their transition process.*
- Information related to the plan's exception and appeals process, including instructions and forms required to file and complete a coverage determination (including an exception) or appeal request.
- Provide a link on their website to the section of CMS' website regarding Best Available Evidence (BAE) policy and make information about BAE policy readily available for those who contact the plan sponsor's call center. Refer to CMS web link: http://www.cms.hhs.gov/PrescriptionDrugCovContra/17_Best_Available_Evidence_Policy.asp.

100.3.1 - Prohibited Links

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Federal Food Drug and Cosmetic Act

Part D plans may not provide links to foreign drug sales on their websites.

100.4 - Required Disclaimers on Websites

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

Plan sponsors must include all applicable explanatory disclaimers as referenced in § 50. *Applicable disclaimers should be placed directly on the web pages of the website; disclaimers contained solely within various documents (e.g., SB) will not suffice.*

100.5 - Enrollment via the Internet

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.60, 422.2268, 423.32, 423.2268

Plan sponsors (except for *section 1876* cost plans) are allowed to accept enrollment requests via the organization's secure Internet website using materials and web pages that have been submitted to CMS for review and received approval. The following information applies to Internet enrollment conducted by a plan sponsor directly.

PDP organization enrollment forms and screens must follow the guidance provided in § 30.1.2 of Chapter 3 of the *Medicare* Prescription Drug Benefit Manual. MA and MA-PD organization enrollment forms and screens must follow the guidance provided in § 40.1.2 of Chapter 2 of the Medicare Managed Care Manual.

Plan sponsors are not permitted to market or enroll beneficiaries in other lines of business/products as part of the online enrollment process.

In developing and submitting online enrollment screens, plan sponsors must include all elements from the applicable model enrollment form, and provide contact information for questions, including toll free telephone and TTY numbers, as well as requirements in Chapters 2 and 3, respectively, of the Medicare Managed Care Manual and the *Medicare* Prescription Drug Benefit Manual.

Following the acceptance of an online enrollment request, the plan sponsor must have a tracking mechanism to provide the individual with evidence that the internet enrollment request was received and in addition, must:

- Offer to send an e-mail or other confirmation to the beneficiary to denote receipt of the online enrollment request; or

- Provide a summary of the plan for which the individual has requested enrollment; or

- Provide a statement that the individual will receive a notice in the mail acknowledging receipt of the completed enrollment request or requesting additional information.

100.5.1 - Required Materials When Online Enrollment is Utilized

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.503, 423.2260

Plan sponsors that choose to allow online enrollment via their website should refer to § 30.***9*** and ensure that all applicable materials are posted in such a manner as to allow beneficiaries the ability to read them prior to accessing an enrollment form. An exception to this is alternate formats (refer to § 90.11 for further details). Apart from compliance with section 508 of the Rehabilitation Act (refer to § 30.8), plan sponsors need only to indicate at the beginning of the online enrollment mechanism that alternate format materials are available by contacting the plan directly. Note that the plan sponsor **cannot** make the Medicare beneficiary read or sign off on these documents as a condition of enrollment; rather, they must only make them available.

110 - Guidance about Value-Added Items and Services

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Chapter 4 of the Medicare Managed Care Manual, § 90

110.1 - Definition of Value-Added Items and Services (VAIS)

(Rev.)

Chapter 4 of the Medicare Managed Care Manual, § 90

The definition, examples, and policy requirements of VAIS are provided in Chapter 4 of the Medicare Managed Care Manual. Plan sponsors should refer to § 170 regarding use of beneficiary information for the provision of information about health-related VAIS. VAIS may be offered by MA plans, PDPs, EGWPs, and section 1876 cost plans.

Because VAIS are not benefits as described within CMS regulations, CMS will not require prior approval of materials solely describing VAIS. If the description of the VAIS is a part of a larger marketing piece, plans must submit the piece in its entirety, but should make the reviewer aware of the VAIS section.

Since VAIS is not a benefit, therefore, it:

- *May not appear in the PBP, SB, ANOC or EOC. Plan sponsors may include VAIS along with their ANOC, SB and/or EOC in one bound brochure as long as the VAIS are clearly distinct from the ANOC, SB or EOC (such as on a different color piece of paper), and the information on VAIS includes the following disclaimer:*

  "The products and services described <below/above> are neither offered nor guaranteed under our contract with the Medicare program. In addition, they are not subject to the Medicare appeals process. Any disputes regarding these products and services may be subject to the <Name of Plan> grievance process."

The above disclaimer should be on all marketing materials if the material mentions VAIS.

120 - Guidance on Marketing and Sales Oversight and Responsibilities

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2272, 422.2274, 423.2272, 423.2274

As provided in § 10, marketing includes any activity of an employee of a plan sponsor, an independent agent, an independent broker or other similar managerial marketing position intended to affect a beneficiary's choice among Medicare plans. Marketing by a person who is directly employed by an organization with which a plan sponsor contracts to perform marketing or a downstream marketing contractor is considered marketing by the plan sponsor. Plan sponsors are responsible for all downstream activities made on their behalf.

120.1 - Compliance with State Appointment Laws

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2272(c), 423.2272 (c)

Plan sponsors must comply with State appointment laws. *In order* to sell Medicare products, **an** agent or broker must be appointed in accordance with the *appropriate* State's appointment law and if there are any fees required as part of the appointment law, the fees must be paid. Note that CMS does not dictate who should pay *any such* fees.

120.2 - Plan Reporting of Terminated Agents

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2272(d), 423.2272(d)

Plan sponsors must report the termination of any brokers or agents, and the reasons for the termination, to the State in which the broker or agent has been appointed in accordance with the State appointment law. Plan sponsors must make the report available upon CMS' request until further guidance has been issued regarding designated reporting dates to CMS.

In addition, plan sponsors should report incidences of submission of applications by unlicensed agents and brokers to the authority in the State where the application was submitted. Agents acting as customer service representatives are not required to hold a license and cannot engage in marketing activities.

120.3 - Agent/Broker Training and Testing

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2274(b)(c), 423.2274(b)(c)

Plan sponsors must ensure annually that brokers and agents selling Medicare products are trained *and tested annually on* Medicare rules and regulations and on details specific to the plan *products that they sell.* To the extent that CMS provides training and testing for agents and brokers, CMS certification will not confer any special advantage to the agents and brokers who participate. Agent and broker use of this certification as a marketing tool will be prohibited.

In order to sell Medicare products, a broker or agent should receive a passing score of at least eighty-five (85) percent on the test of Medicare rules and regulations. Tests may be written or computerized. Plan sponsors must ensure that their training and testing programs are designed and implemented in a way that the integrity of the training and testing is maintained. In doing so, they must have a process for handling instances in which agents do not pass the test on the first try. Plan sponsors should document that each agent/broker has been trained and must have the ability to provide this information to CMS upon request.

120.4 - Agent/Broker Use of Marketing Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2262, 423.2262

Plan sponsors are responsible for all marketing materials used by their subcontractors to market their plan(s). All marketing materials used by plan sponsors or their subcontractors must be submitted by the plan sponsor to CMS for review and approval prior to use. Marketing materials **cannot** be submitted directly by a third party to CMS.

Agents and brokers are permitted to create and distribute materials, such as a business card indicating the products (for example HMO, PPO, or PDP) that he/she is selling for a specific plan or plan(s) without CMS review. This limited flexibility to use materials without submitting them to CMS for review only applies to agent and/or broker materials that do not meet the

definition of marketing materials in § 20. Materials that do meet the definition of marketing materials must be submitted to CMS for review and approval or acceptance via the plan sponsor. Please note that this guidance in no way precludes the application by the plan sponsors of more stringent rules or contractual obligations in order to further restrict agent or broker communication.

Additionally, agent/brokers who wish to use materials containing plan information from multiple plan sponsors can either have one plan sponsor submit the material on behalf of all the other sponsors, or have the piece submitted and approved by CMS for each plan sponsor mentioned prior to use.

120.5 - Agent/Broker Compensation

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2274(a), 423.2274(a)

Plan sponsors are not required to use independent agents and brokers, but if they do they must follow CMS rules for compensating them for the sale of Medicare products. CMS has established limits on agent and broker compensation in order to ensure that compensation does not create incentives for agents and brokers to assist beneficiaries with plan selection using criteria other than the beneficiaries' health care needs and preferences. These limits apply to MA organizations, Part D sponsors, and section 1876 cost plans that market through independent brokers or agents. These compensation rules are designed to eliminate inappropriate moves of beneficiaries from one plan to another. These compensation rules do not apply to employed agents or employer group plans.

120.5.1 - *Definition of Compensation*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2274(a), 423.2274(a)

For purposes of this chapter, compensation includes pecuniary or non-pecuniary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes, awards, and finder's fees.

Compensation **DOES NOT** include the following *(note that the following list represents examples, but not an all-inclusive list of, activities that are excluded from the definition of compensation* :

- The payment of fees to comply with State appointment laws
- Training

- Certification
- Testing costs
- Reimbursement for mileage to, and from, appointments
- Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials

120.5.2 - *Compensation Types*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2274(a) (3), 423.2274(a) (3)

The regulations provide for two types of compensation -- initial compensation and renewal compensation.

Initial compensation is offered for the beneficiary's initial year of enrollment in a plan. Renewal compensation is equal to fifty (50) percent of the initial compensation amount and is paid in the five (5) years following a beneficiary's initial year of enrollment in a plan. It is also paid when a beneficiary enrolls in a different plan but one that is a "like plan type" following the initial year of enrollment.

NOTE: *Renewal compensation will apply whether or not the new enrollment is in a plan offered by the same or a new (receiving) organization (e.g., the member moves to a different plan within the same parent organization).*

A "like plan type" moves refer to moves from:

- A PDP to another PDP,
- An MA or MA-PD to another MA or MA-PD, or
- *A section 1876 cost plan to another section 1876 cost plan*

"Unlike plan type" moves refer to moves from:

- *An MA or MA-PD plan to a PDP or section 1876 cost plan,*
- *A PDP to a section 1876 cost plan or an MA (or MA-PD) plan, or*
- *A section 1876 cost plan to an MA (or MA-PD) plan or PDP.*

NOTE: For dual enrollments (e.g., enrollment in an MA-only plan and a stand-alone PDP), the compensation rules apply independently to each plan. However, when dual enrollments are replaced by an enrollment in a single plan, compensation is paid

based on the MA movement (e.g., movement from an MA-only plan and PDP to an MA-PD plan would be compensated at the renewal compensation amount for the MA to MA-PD "like plan type" move).

120.5.3 - Compensation Cycle (6-Year Cycle)

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2274(a), 423.2274(a)

After a beneficiary is enrolled in an MA plan or PDP by an agent or broker, a renewal compensation would be paid for five years after the initial compensation year, creating a six (6)-year compensation cycle. However, if an enrollee moves to a plan of a different plan type, the agent or broker may receive *an initial compensation and the six (6)-year cycle starts over again. Once the compensation cycle expires, it does not restart until the beneficiary enrolls into another plan. Plan sponsors may continue to pay agents or brokers renewal compensation beyond the six (6)-year cycle at the plan's discretion, as described in § 120.5.4. The monthly MARx agent/broker compensation report that is generated when an enrollment occurs will provide plan sponsors with the information necessary to determine whether they should make an initial or renewal payment*.

120.5.4 - Specific Guidance for Developing and Implementing Compensation Strategy

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2274(a), 423.2274(a)

Following is specific guidance for plan sponsors as they develop or modify their agent/broker compensation strategy.

- CMS defines "year" as a plan year, meaning January 1 through December 31. *For example, if a beneficiary turns 65 in and enrolls in a plan in September, then the initial year for that beneficiary ends on December 31st of that year, even though the beneficiary has only been in the plan for four months. In January of the next year, the plan would begin paying renewal payments to the agent that assisted this beneficiary. When a beneficiary enrolls after January 1, the plan sponsor must pay the agent/broker at the initial compensation level during that calendar year but may pay either the full commission or a pro-rated amount based upon the number of months the beneficiary was enrolled. The plan sponsor has the discretion to provide this compensation in a single payment or multiple payments at anytime during the year. Compensation of the agent/broker for the remainder of the six (6)-year commission cycle must be at the renewal commission level. The renewal commission may also be paid at any time during each year of the cycle and may be paid in a single payment or multiple payments*.

- For the purpose of calculating compensation, the movement by a beneficiary from an employer group plan to an individual plan (either within the same plan sponsor or between different plan sponsors) counts as an initial enrollment.

- *Plan sponsors must not pay agents who are no longer appointed to sell in the State (if required), agents who have not been annually trained and tested per the plan's policies and procedures with a passing score of eighty-five (85) percent, or agents who have been terminated for cause by the plan.*

- CMS does not differentiate between agents, brokers, general agents, general agencies, FMOs, and distribution partners. It is the plan sponsor's responsibility to ensure that all of its contracted sales staff's compensation levels abide by CMS rules.

- CMS compensation requirements do not apply to employed agents.

- If a contracted agent receives a base salary and sells exclusively for one plan sponsor, that agent may be considered employed for purposes of applying CMS agent/broker compensation requirements.

- While CMS does not dictate how plans should pay compensation (e.g., monthly, quarterly, annually), CMS prohibits plans from paying compensation in advance (e.g., paying five (5) years' residuals up front).

- *Referral fees are equivalent to finder's fees and governed by CMS regulations. This means that referral fees must be included in compensation schedules and fall within CMS compensation rules. While referral fees are part of total compensation, they are a one-time fee and not subject to the six (6)-year compensation cycle.*

- *Bonuses (announced or unannounced prior to payment) must be included in compensation schedules and fall within CMS rules. A bonus does not fall outside CMS rules because it was not announced to agents or brokers in advance.*

- Compensation for dual enrollments should be paid independently (e.g., when a beneficiary enrolls in both a *section 1876* cost plan and a standalone PDP, compensation should be paid for both enrollments.)

- When a beneficiary enrolls in an MA-PD plan, compensation should be paid using the MA compensation amount. Plan sponsors should not pay both the MA and PDP compensation amounts.

- *For Medicare beneficiaries enrolling in a plan mid-year and having no prior plan history as indicated on the compensation report, plan sponsors may pay the full year initial compensation amount.*

- *A plan sponsor will have the opportunity prior to each contract year to determine that it will no longer use independent agents and brokers. When a plan sponsor and/or a*

contracted independent agent or broker elect to terminate their contract, any remaining cycle years of existing business will be governed by the terms of that contract.

120.5.4.1 - Additional Marketing Fees

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2274(a), 423.2274(a)

A plan sponsor may not charge a beneficiary or allow its marketing representatives to charge a beneficiary a marketing fee outside of the approved premium for the purpose of compensating a marketing representative. All costs associated with the marketing of a plan are the responsibility of the plan sponsor. An enrollee cannot be held responsible for the cost of marketing beyond the base premium. Any such costs are considered part of the plan sponsor's administrative costs and must be included in the plan sponsor's bid submission.

120.5.5 - Compensation Calculation

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2274(a), 423.2274(a)

The aggregate compensation amount paid for selling or servicing an enrollee during each of the five individual renewal years of a six (6)-year cycle must be fair-market value *(FMV)* for the work performed and no more, and no less, than fifty (50) percent of the aggregate compensation amount paid for that beneficiary in the initial year of the six-year. In addition, all parties should ensure that their compensation arrangements including arrangements with *FMO*s and other similar type entities comply with all fraud and abuse laws, including the Federal anti-kickback statute.

120.5.6 - *Specific Guidance for Recovering Compensation Payments (Charge-backs)*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2274, 423.2274

Plans are required to recover compensation payments from agents under two circumstances: 1) when a beneficiary disenrolls from a plan within the first three months of enrollment (rapid disenrollment) and 2) any other time a beneficiary is not enrolled in a plan.

***Note**: When a member enrolls in a plan effective October 1, November 1, and December 1, and subsequently changes plans effective January 1 of the following year, it is not considered a rapid disenrollment. Therefore, plans cannot charge back agent*

compensation payments, If, however, a beneficiary enrolls in October and disenrolls in December, then the plan should charge back because of a rapid disenrollment.

***Example 1** – A beneficiary enrolls in Plan D with an effective date of February 1. In April, the beneficiary disenrolls. Since the beneficiary rapidly disenrolled, Plan D must recover all compensation paid for that enrollment.*

Example Table 1:

	Enrollment Effective Date	**Disenrollment Effective Date**
Beneficiary	February 1	April 1
Plan (D)	Pays agent monthly amount.	Recovers all payments for this enrollment because it is a rapid disenrollment (it occurs within the first 3 months of enrollment in the plan).

***Example 2** – A beneficiary enrolls in Plan G effective in March 1. Several months later the beneficiary decides to enroll in Plan T with an effective date of November 1st. If plan G has paid the agent for March through December, then it must recover compensation from the agent for November and December. If the beneficiary changes plans in January of the following year, the plan sponsor does not recover payments made from November and December because this is not a rapid disenrollment.*

Example Table 2:

	Enrollment Effective Date	**Disenrollment Effective Date**	**2nd Enrollment Effective Date**	**Following Contract Year**
Beneficiary	March 1	November 1	November 1	
Plan (G)	Pays agent a prorated amount for March through December.	Plan sponsor recovers payments for November through December.		
Plan (T)			Pays agent for November through December.	Does not recover any payments from the previous year.
Plan (X)				Makes

				payments for the following year.

Example 3 *– An agent enrolls a beneficiary in Plan K with an effective date of January 1st. The beneficiary is subsequently disenrolled because the plan was not able to verify eligibility information. In March, the plan receives the necessary information to verify the enrollment. The beneficiary is re-enrolled in the plan. The plan must pay the agent for the entire time the beneficiary is enrolled in the plan (including when enrollment is retroactive).*

Example Table 3:

	Enrollment Effective Date	**Disenrollment Effective Date**	**2nd Enrollment Effective Date**
Beneficiary 1	January 1	January 20	March 1 (retroactive to January 1)
Plan (K)	Pays agent for entire year.	Recovers payment due to rapid disenrollment.	Pays agent for entire year because the retroactive enrollment.
Beneficiary 2	January 1	January 20	March 1 (retroactive to January 1)
Plan (K)	Pays agent for first month.	Recovers payment for first month.	Pays agent for January, February, and March and continues making payments each month that the beneficiary remains in the plan.

Example 4 *– A beneficiary enrolls in Plan A with an effective date of January 1. In May, the beneficiary enrolls into Plan B. In October, the beneficiary decides to change plans again. This time the beneficiary enrolls in Plan Z. Plan A is responsible for paying the agent through April. Plan A must recover any payments made that cover May through December. Plan B is responsible for paying compensation for May through September. Plan B should not have paid anything to the agent for January through April because Plan A was responsible for those payments. Additionally, Plan B is responsible for recovering any payments covering October through December. Finally, Plan Z is responsible for paying the agent from October through December. Plan Z should not have paid anything to the agent for January through September. If the member changes plans in January of the following year, Plan Z cannot chargeback for October through December because this is not a rapid disenrollment.*

Example Table 4:

	Enrollment Effective Date	**Disenrollment Effective**	**2nd Enrollment Effective Date**	**Disenrollment Effective**	**3rd Enrollment Effective**	**Following Contract Year**

		Date		Date	Date	
Beneficiary	January 1	May 1	May 1	October 1	October 1	January 1
Plan (A)	Pays agent the agent the yearly amount.	Recovers payments from the agent for the months of May through December.				
Plan (B)			Pays agent a monthly amount for each month the beneficiary is a member of the plan beginning with May.	Recovers nothing. Only paid for actual months the beneficiary was a member of the plan.		
Plan (Z)					Pays agent quarterly amount (covering the months of October, November and December).	Does not recover any payments from previous year.
Plan (T)						Makes payments for the new year.

Plans should not recover funds (but should pay only for the actual months the beneficiary is enrolled in the plan) when a beneficiary disenrolls within the first three months under the following circumstances:

- *The beneficiary qualifies for one of the following special election periods (SEP):*
    - *Disenrollment from Part D due to:*
        - *Other creditable coverage; or*
        - *Institutionalization;*

- *Under the following exceptional circumstances:*
  - *Gains/drops employer/union sponsored coverage;*
  - *Because of a CMS sanction against the plan;*
  - *Because of plan terminations;*
  - *Because of a non-renewing section 1876 cost plan;*
  - *During the Medigap trial period;*
  - *In order to coordinate with Part D enrollment periods; or*
  - *In order to coordinate with an SPAP;*

- *Due to following changes in status:*
  - *Becoming dually eligible for both Medicare and Medicaid;*
  - *Qualifying for another plan based on special needs;*
  - *Becoming LIS eligible;*
  - *Qualifying for another plan based on a chronic condition; or*
  - *Moves into or out of institution;*

- *Due to an auto– or facilitated enrollment*

- *The beneficiary is involuntarily disenrolled for one of the following reasons:*
  - *Death;*
  - *Moves out of the service area;*
  - *Non-payment of premium;*
  - *Loss of entitlement;*
  - *Retroactive notice of Medicare entitlement;*
  - *Contract violation; or*
  - *Plan non-renewal or termination*

120.5.7 - Adjustments to Compensation Schedules

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2274, 423.2274

For 2010 and subsequent years, the compensation amount paid to an agent or broker for enrollment of a Medicare beneficiary into a plan sponsor's plan is as follows:

- *For an initial enrollment, the prior year's initial compensation adjusted by the change in MA or Part D rates announced in the "Announcement of Calendar Year Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies" for that contract year.*

- *For renewals, an amount equal to fifty (50) percent of the initial compensation. The broker or agent is paid a renewal compensation for each of the next five (5) years the enrollee remains in the plan in an amount equal to fifty (50) percent of the initial year compensation amount (creating a six (6)-year compensation cycle).*

- *Plan sponsors with plans for which they created compensation schedules in prior years can only adjust existing compensation schedules; they may not create any new compensation schedules for those plans.*

New compensation schedules (no schedules existed for prior years) are allowed:

- *For plans that did not exist in prior years by selecting a compensation amount that is at or below the adjusted fair market value cut-off amounts.*

- *For plans that existed in prior years but did not have an associated compensation schedule (i.e., the plan chose to compensate $0 for enrollments in that particular product) by selecting a compensation amount that is at or below the adjusted fair market value cut-off amount.*

Plan sponsors that consolidate plans from one contract year to the next may:

- *Associate with the consolidated plan all, or a subset, of the prior year's schedules associated with the set of plans being consolidated. These schedules must be adjusted relative to the previous year's schedules according to the rate adjustment guidelines.*

- *Only adjust all or a subset of the existing compensation schedules associated with plans for which compensation schedules were created the previous year; they may not create any new compensation schedules for the consolidating plans.*

Plan sponsors that are undergoing service area expansions/reductions:

- *Cannot create new compensation schedules or use in the reduced service area schedules associated with the geographic areas that are no longer part of their new service area.*

- *May create new compensation schedules only in the portion of the expanded service area that cross State boundaries when they are expanding an existing service area and it crosses State boundaries.*

120.5.8 - *Third Party Marketing Entities*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2274(a), 423.2274(a)

If the plan sponsor contracts with a third party entity such as a FMO or a similar type of entity to sell its insurance products or perform services (for example, training, customer service, or agent recruitment), the amount paid to the third party must be *of fair market value* and must not exceed an amount that is commensurate with the amounts paid by the plan sponsor to a third party for similar services during each of the previous two (2) years.

120.6 - *Activities That Do Not Require the Use of State-Licensed Marketing Representatives*

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2274(c), 423.2274(c)

Some plan activities, typically carried out by the plan sponsor's customer service department do not require the use of State-licensed marketing representatives. These include the following:

- Providing factual information
- Fulfilling a request for materials
- Taking demographic information in order to complete an enrollment application at the initiative of the *prospective e*nrollee

These examples are legitimate customer service activities that would not require using State-licensed marketing representatives. A State-licensed representative is required when marketing as defined in § 20 is performed.

To further clarify, when employee customer service representatives, employed or contracted agents, and/or external agents and brokers perform customer service functions, such as answering questions and/or accepting enrollments on behalf of *prospective* enrollees who have already decided to *request enrollment* in a particular plan offered by the plan sponsor, these functions are considered legitimate customer service representative activities and do not trigger the need to use a State-licensed marketing representative. All required CMS enrollment procedures and guidance apply.

Plan sponsors are reminded that they may not require potential enrollees to interact with a licensed agent in order to obtain plan material or to enroll in a plan if the potential enrollee is not asking for advice or counseling. Further, agents cannot act as a customer service representative and agents simultaneously. When agents acting as a customer service representative encounter questions from beneficiaries that are beyond the scope of a customer service representative, they must transfer the caller to an agent who is not acting as a customer service representative.

130 - Guidelines Applicable to Employer/Union Group Health Plans

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

1857(i), 1860D-22(b), 42 CFR 422.2276, 423.2276

As provided in § 10.1 of Chapter 9 of the Medicare Managed Care Manual and § 10.1 of Chapter 12 of the Prescription Drug Benefit Manual, CMS has authority under sections 1857(i) and 1860D-22(b) of the Social Security Act to waive or modify requirements that hinder the design of, the offering of, or the enrollment in employment-based Medicare plans offered by employers and unions to their members. Waivers and modifications may be granted to plan sponsors offering "individual" PDPs or MA plans, or plan sponsors offering customized employer group PDPs or MA plans offered exclusively to employer/union group health plan sponsors (known as employer/union-only group waiver plans, or EGWPs). CMS has issued various employer group waivers and/or modifications to the Medicare Part C and Part D rules for marketing and disclosure/dissemination of information to Medicare beneficiaries. For specific guidance regarding these waivers or modifications of marketing and disclosure/dissemination of information requirements for employer/union-sponsored group health plans, please refer to § 20.3 of Chapter 9 of the Medicare Managed Care Manual, and § 20.3 of Chapter 12 of the Prescription Drug Benefit Manual.

Plan sponsors offering employer group health plans are no longer required to submit informational copies of their dissemination materials to CMS at the time of use. However, as a condition of CMS providing these particular waivers or modifications, CMS reserves the right to request and review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan. For more information about these requirements, refer to § 20.3.2.1.1 of Chapter 9 of the Medicare Managed Care Manual, and § 20.3.2.1.1 of Chapter 12 of the Prescription Drug Benefit Manual.

In addition to the guidance specific to marketing materials, much of the procedural guidance as outlined in this chapter is also applicable to employer plans. Please reference the grid below for further guidance on the applicability of the various requirements.

Table 130-1. Marketing Provisions – Employer/Union Group Plans

Marketing Provisions that apply to Employer/Union Group Plans (these requirements are applicable for the transaction between the agent/broker selling the plan to the employer/union. All activities conducted by the employer/union or its designees to sign up individual

employees to the plan(s) selected by the employer/union are excluded from these provisions.)		
Provision	**Yes**	**No**
Nominal Gifts	X	
Unsolicited Contacts		X
Cross-selling		X
Scope of Appointments		X
Sales/Marketing in Health Care Settings	X	
Sales/Marketing at Educational Events	X	
Co-branding	X	
Provision of Meals		X
Appointment of Agents/Brokers	X	
State Licensed	X	
Reporting of Terminated Agents/Brokers	X	
Agent/Broker Compensation		X
Agent/Broker Training and Testing – Agents must be thoroughly familiar with the products they are selling; including the plan specific details and the Medicare rules that apply to the specific products. The organization/sponsor is responsible for ensuring that the agents selling for them have sufficient knowledge.	X (training)	X (testing)

140 - Special Guidance for Medicare Medical Savings Account (MSA) Plans

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

MSAs are required to abide by all applicable guidance set forth in this chapter.

140.1 - MSA General Advertising Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

General advertisement materials, as defined by these *Medicare Marketing G*uidelines, created to promote MSAs must adhere to all applicable guidance in § 50. In addition, due to the unique nature of MSAs, MSA plan marketing materials should:

- Include the standard definition of an MSA:

  > *"MSA Plans combine a high deductible Medicare Advantage Plan and a bank account. The plan deposits money from Medicare into the account. You can use the money in this account to pay for your health care costs, but only Medicare-covered expenses count toward your deductible. The amount deposited is usually less than your deductible amount, so you generally will have to pay out-of-pocket before your coverage begins."*

- Display "(MSA)" or "(Medical Savings Account)" in all headers of all marketing displays.

- Include the member's obligation to continue to pay Medicare Part B premiums, as well as the fact that there are no plan premiums.

- Not imply that an MSA plan functions as a supplement to Medicare.

- Not use the term "network" to describe a list of contracted preferred providers, if available.

- Include the following statement:

  > *"Medicare MSA Plans don't cover prescription drugs. If you join a Medicare MSA Plan, you can also join a Medicare Prescription Drug Plan to get drug coverage."*

  NOTE: MSAs **cannot** offer Part D but enrollees can enroll in a separate PDP plan. MSAs should reference all of the MA and PDP plan sponsors' offerings, and not just the MSA plan so the beneficiary knows that he/she can choose any PDP and is not restricted to the MSA plan sponsor's own PDP offering. (42 CFR 422.4(c)(2))

- Provide specific information to beneficiaries related to all aspects of the MSA plan's cost-sharing, especially what is and is not counted towards the deductible,

and how the MSA accounts are invested, the nature of the risk associated with the accounts, and the record of return on investments over the last two years.

140.2 - MSA Explanatory Marketing Materials Requirements

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

42 CFR 422.2264, 423.2264

Explanatory marketing materials, as defined in this chapter, created to promote MSAs must adhere to all applicable guidance found in § 50.4. In addition, due to the unique nature of MSAs, plan sponsors must also include the following information in explanatory marketing materials for MSA plans.

- Explain that Medicare beneficiaries are not eligible for an MSA plan if they:
    - Have health coverage that would cover Medicare MSA plan deductibles, including benefits under an employer or union group health plan. (42 CFR 422.56(d))
    - Are eligible for health care benefits through the Department of Defense (TRICARE) or the Department of Veteran Affairs (VA). (42 CFR 422.56(b))
    - Are enrolled in a Federal Employees Health Benefits Program (FEHBP). (42 CFR 422.56(b))
    - Are eligible for Medicaid. (42 CFR 422.56(c))
    - Have end stage renal disease (permanent kidney failure requiring dialysis or a kidney transplant).
    - Are currently getting hospice care.
    - Live outside of the United States more than one hundred eighty three (183) days a year. (42 CFR 422.56(a))
- Explain the unique features of MSA plans, including the MSA trustee arrangement, costs to the member before and after the deductible is met, what costs count towards the deductible, how they are tracked by the plan and what happens to the money in the account if the member leaves the plan.
- Include the following statement:

    "Enrollment is generally for the full calendar year. You can disenroll from <Plan Name> between [for AEP in 2010 for CY 2011, insert: November 15 and

December 31][for AEP in 2011 and later for CY 2012 and beyond, insert October 15 and December 7]1 of each year. Your disenrollment will be effective January 1 of the next year. You may not disenroll or make changes at other times unless you meet certain special exceptions, such as if you move out of the plan's service area, qualify for Medicaid, or qualify for Extra Help with Medicare prescription drug costs. Those who disenroll during the calendar year will owe a portion of the account deposit back to the plan."

- Include the following statement to explain a member's tax responsibility:

  "You must file Form 1040, US Individual Income Tax Return, along with Form 8853, "Archer MSA and Long-Term Care Insurance Contracts" with the Internal Revenue Service (IRS) for any distributions made from your Medicare MSA account to ensure you aren't taxed on your MSA account withdrawals. You must file these tax forms for any year in which an MSA account withdrawal is made, even if you have no taxable income or other reason for filing a Form 1040. MSA account withdrawals for qualified medical expenses are tax free, while account withdrawals for non-medical expenses are subject to both income tax and a fifty (50) percent tax penalty."

- Include the following language with the associated links to members for their information:

  - *"For more information about MSA plans, visit www.medicare.gov/Publications/Pubs/pdf/11206.pdf to view the booklet "Your Guide to Medicare Medical Savings Account Plans."*
  - *"Tax publications are available on the IRS website at http://www.irs.gov or from 1-800-TAX-FORM (1-800-829-3676).*

150 - Use Of Medicare Mark For Part D Plans

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

All MA-PD plans, PDPs, section 1876 cost and PACE plans that provide Part D benefits will submit a licensing agreement to use the official Medicare Mark via HPMS. CMS will issue additional guidance on this process.

150.1 - Authorized Users for Medicare Mark

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

All MA-PD plans and PDPs are authorized to use the Medicare Prescription Drug Benefit Program Mark only after receiving written communication from CMS. This communication will include a licensing agreement which must be signed by the organization's CEO/CFO or designee in order to use the Medicare Prescription Drug Benefit Program Mark prior to execution of the Part D contract. The Part D contract contains provisions regarding the use of the mark. PDP and MA-PD entities may use the mark on submission of marketing materials consistent with this chapter.

150.2 - Use of Medicare Prescription Drug Benefit Program Mark on Items for Sale or Distribution

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

All PDP and MA-PD entities may use the Medicare Prescription Drug Benefit Program Mark on items they distribute, provided the item(s) follow(s) guidelines for nominal gifts, as provided in § 20 and 70.2. Items with the Medicare Prescription Drug Benefit Program Mark **cannot** be sold for profit.

150.3 - Approval to Use the Medicare Prescription Drug Benefit Program Mark

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

CMS has established the following process to grant authorized users the use and access to the Medicare Prescription Drug Benefit Program Mark on Part D marketing materials.

For those organizations that have received "conditional approval" of a Part D plan via the CMS application and HPMS contract approval process, CMS will distribute the Medicare Prescription Drug Benefit Program Mark licensing agreement to those entities. Organizations are to

certify/attest that they will use the mark according to the guidance in this chapter. After CMS has received the signed licensing agreement back from the organizations, the Medicare Mark URL will be sent to the organizations.

After receipt of the URL, organizations may begin using the mark on marketing materials (including the Part D membership ID card) that are required to be submitted to CMS for review.

Organization requests to distribute other items (materials that are not included in this chapter) bearing the Medicare Prescription Drug Benefit Program Mark must be submitted to CMS at least thirty (30) days prior to the anticipated date of distribution. Requests should be sent to: CMS External Affairs Office/Visual & Multimedia Communications Group at 7500 Security Blvd., Baltimore, MD 21244-1850, Mail Stop: C1-16-03.

Once a request has been approved the following will apply: 1) approval will be effective for a period not to exceed one year or at the time of termination from the Part D program, and 2) approval will be granted only for those items for which use of the mark was requested in the request letter and for which written approval was granted.

150.4 - Restrictions on Use of Medicare Prescription Drug Benefit Program Mark

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

Unless otherwise approved, all unauthorized individuals, organizations, and/or commercial firms may not distribute materials bearing the Medicare Prescription Drug Benefit Program Mark.

Unauthorized use of the Medicare Prescription Drug Benefit Program Mark should be reported immediately so that appropriate legal action can be taken. Reports of unauthorized use should be referred to CMS's External Affairs Office at 7500 Security Blvd., C1-16-03, Baltimore, MD 21244-1850, or by telephone to 410.786.7214.

150.5 - Prohibition on Misuse of the Medicare Prescription Drug Benefit Program Mark

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act and 42 U.S.C. §1320b-10

42 U.S.C. §1320b-10 prohibits the misuse of the Medicare name and marks. In general, it authorizes the Inspector General of the Department of Health and Human Services (DHHS) to impose penalties on any person who misuses the term Medicare or other names associated with DHHS in a manner which the person knows or should know gives the false impression that it is

approved, endorsed, or authorized by DHHS. Offenders are subject to fines of up to $5,000 per violation or in the case of a broadcast or telecast violation, $25,000.

150.6 - Mark Guidelines

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

The Medicare Prescription Drug Benefit Program Mark is a logotype comprised of the words Medicare Rx with the words Prescription Drug Coverage directly beneath.

Always use reproducible art available electronically. Do not attempt to recreate the Program Mark or combine it with other elements to make a new graphic. Artwork will be supplied in .EPS, .TIFF or .JPG format after notification of approval into the program. Other file formats are available from CMS's Office of External Affairs upon request.

150.6.1 - Mark Guidelines - Negative Program Mark

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

The Medicare Prescription Drug Benefit Program Mark may be reversed out in white. The entire mark must be legible.

150.6.2 - Mark Guidelines - Approved Colors

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

The two (2)-color mark is the preferred version. It uses PMS 704 (burgundy) and sixty-five (65) percent process black. It is recommended that if the CMS mark is used in conjunction with the brand mark, that the black versions of those logos be used.

The 1-color version in grayscale is acceptable. The mark elements are one-hundred (100) percent black except for the word “Medicare” which is fifty-five (55) percent black.

The 1-color version in one-hundred(100) percent black also is acceptable.

150.6.3 - Mark Guidelines on Languages

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

The Spanish version of the Medicare Prescription Drug Benefit Program Mark may be used in place of the English language version on materials produced entirely in Spanish. The two (2)-color version is preferred, but the grayscale, black and negative versions may be used.

150.6.4 - Mark Guidelines on Size

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

To maintain clear legibility of the Program Mark, never reproduce it at a size less than one (1) inch wide. The entire mark must be legible.

150.6.5 - Mark Guidelines on Clear Space Allocation

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

The clear space around the Medicare Prescription Drug Benefit Program Mark prevents any nearby text, image or illustration from interfering with the legibility and impact of the mark. The measurement “x” can be defined as the height of the letter “x” in “Rx” in the Program Mark. Any type or graphic elements must be at least “x” distance from the mark as shown by the illustration.

150.6.6 - Mark Guidelines on Bleed Edge Indicator

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

The Program Mark may not bleed off any edge of the item. The mark should sit at least one-eighth (1/8) inch inside any edges of the item.

150.6.7 - Mark Guidelines on Incorrect Use

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

Following are rules for preventing incorrect use of the Medicare Prescription Drug Benefit Program Mark:

- Do not alter the position of the mark elements.
- Do not alter the aspect ratio of the certification mark. Do not stretch or distort the mark.
- Always use the mark as provided.
- Do not rotate the mark or any of its elements.
- Do not alter or change the typeface of the mark.
- Do not alter the color of any of the mark elements.
- Do not position the mark near other items or images. Maintain the clear space allocation.
- Do not position the mark to bleed off any edge. Maintain one-eight (1/8) inch safety from any edge.
- Do not use any of the mark elements to create a new mark or graphic.
- Do not use the mark on background colors, images or other artwork that interfere with the legibility of the mark.

150.7 - Part D Standard Pharmacy ID Card Design

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Section 1140 of the Social Security Act

Usage of the Medicare Prescription Drug Benefit Program Mark on any item must be consistent with § 60.2 of this chapter.

160 - Use of Federal Funds

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

(Division F, Title V, § 503(b), Departments of Labor, HHS, and Education Appropriations Act, 2009, as enacted by § 5, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 123 Stat. 524, 802 (March 11, 2009))

CMS prohibits the use of Federal funds for non-plan related activities that are designed to influence State or Federal legislation or appropriations, by MAOs, Part D sponsors, section 1876 cost plans, PACE plans, and MA demonstration plans. Specifically, the Department of Health and Human Services' annual appropriations acts very specifically that no appropriated funds may be used to pay the "salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature."

170 - Allowable Use of Medicare Beneficiary Information Obtained from CMS

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

All MA, Part D, PACE, and section 1876 cost plans sign a data use attestation under which they agree that they will restrict the use of Medicare data to those purposes directly related to the administration of the Medicare managed care and/or outpatient prescription drug benefits for which they have contracted with CMS to administer. Plan sponsors also agree not to use that information to develop, market, or operate lines of business unrelated to their Medicare plan operations.

For purposes of these Data Use Attestations, CMS-provided data includes information provided by beneficiaries in the course of their enrollment in a Medicare plan as well as data obtained solely as a result of access to CMS systems granted to the contracting organization or sponsor because it is a Part C, Part D, PACE or section 1876 cost plan contractor. Except in cases in which the enrollee gave information as part of a commercial relationship prior to enrollment *in the Medicare plan, the contracting organization or sponsor was only given the information on the application as a result of the contract with CMS.*

While plan sponsors with a previous commercial relationship with Medicare beneficiaries (and employers offering Medicare plans) may have obtained their personal data through that relationship, and therefore are not obligated to follow the guidelines set forth in the Data Use Agreement, we encourage plan sponsors to follow these data use guidelines as a good business practice for protecting beneficiaries from potentially unwelcome marketing and other communications. Examples of what is considered a previous commercial relationship include membership in such products as:

- *Long-term care insurance*
- *Life-insurance policies*
- *Non-Medicare employer or retiree plans*
- *Medigap policies*

While it is important to protect Medicare beneficiaries from potentially unwelcome marketing and other communications, we also recognize plan sponsors interest in contacting their enrollees on issues unrelated to the specific plan benefit that they contract with CMS to provide to those enrollees. This section contains additional guidance for plan sponsors on the distribution of other types of non-plan related information.

170.1 - When Prior Authorization From the Beneficiary Is Not Required to Use Beneficiary Information Obtained from CMS

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

As specified in § 40.14.1, plan sponsors are permitted to send current members information about health-related issues without any prior authorization from the beneficiary, as long as the material includes instructions describing how the individuals may opt-out of receiving such communications. In addition, plan sponsors may send current members information about health-related VAIS provided those materials contain opt-out instructions. Examples of health-related issues plan sponsors may communicate without receiving the prior authorization of current enrollees include:

- *Long-term care insurance*
- *Separate dental or vision policies*
- *Value-added items and services (VAIS)*

Plan sponsors may provide information to their existing enrollees about current plan coverage and other MA plan, PDP, cost plan, or Medigap products offered by the plan sponsor without any prior authorization from enrollees. Provided that the information is not confusing or misleading, or includes references to information that requires prior authorization, plan sponsors may provide relevant plan and health information to members, including monthly newsletters, information on disease management programs, mailings describing rationale for benefits changes and information on Medicaid and other community or social services program.

170.2 - When Prior Authorization From the Beneficiary Is Required to Use Beneficiary Information Obtained from CMS

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

As specified in § 40.14.5, plan sponsors are permitted to send current enrollees information about non-health related services/issues, provided they obtain authorization from an enrollee prior to using an enrollee's protected health information to provide marketing/information about an item or service that is not health-related. Examples of non-health related issues plans may communicate after receiving prior authorization ("opt-in") of current enrollees include:

- *Accident-only policies*
- *Life insurance policies*
- *Annuities*

Other materials distributed to members that are unrelated to the administration of plan benefits, or are not related to health-related issues or other lines of business offered by the same organization, are also subject to the prior authorization ("opt-in") requirements. Examples of these types of issues include information on:

- *Volunteer or community activities*
- *Pending State or Federal legislation*
- *Joining grassroots advocacy organizations and information about such advocacy*

Both written and oral communications designed to facilitate non-health or non-plan related activities require prior authorization.

170.3 - Obtaining Prior Authorization

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Following are examples of how the prior authorization required under § 170.2 may be obtained. With any of these examples, plan sponsors must receive the member's "opt-in" authorization prior to receiving any non-plan or non-health related information, and plan sponsors should keep evidence of authorization for audit purposes.

- *Plan sponsors may send, at their own expense, written requests to enrollees to obtain the beneficiary's authorization for the organization or sponsor to contact him/her for purposes unrelated to plan benefits administration or CMS contract execution. The beneficiary must sign and return the request before the plan can send non-plan related materials or information. This authorization may also be obtained by directing a beneficiary to a website to provide the requisite consent. Note that if the plan uses a website for the "opt-in" process, the link from the plan's Medicare product website must inform the beneficiary that he or she is leaving the Medicare product website and going to the non-Medicare product website, as provided in § 100.1. Once a beneficiary "opts-in" the plan sponsors must be clear that the beneficiary will receive additional information that may be non-plan or non-health related.*

- *Beneficiaries can complete authorization in person at marketing events, health fairs, or other public venues.*

- *Beneficiaries can complete the authorization over the telephone, provided that the authorization is recorded. The call must be a beneficiary-initiated inbound telephone call and scripts for such calls must comply with all guidance in § 80.*

- *Beneficiaries can complete the authorization via an email to the plan, provided that the authorization includes an electronic signature.*

Regardless of the method by which the prior authorization is obtained (e.g., written, telephonic, on a website), the following rules apply:

- *The request may include one or more types of information for which authorization is being sought. If more than one type of information is on the form, a check box (or verbal agreement, if a telephonic authorization) needs to be assigned to each type of information. Furthermore, the type of information can only be described in general terms. For example, "Check the boxes of the types of information you would like to receive: life insurance, long-term care insurance, pending State and Federal legislation, grass-roots advocacy."*

- *The request for authorization should not include any non-plan or non-health related content, nor should it be included in the same mailing as information on non-health related issues, unless the plan sponsor has previously received prior authorization to send that particular non-health related information to that member. (For example, a request for authorization to send information about life insurance should not include a statement like "Make sure your spouse's future is secure, with a life insurance policy from us," and/or should not be sent with documents that include details about the life insurance policy.)*

- *The request for authorization can be included in the same mailing as plan-related or health-related mailings to members, as provided in these Medicare Marketing Guidelines (including § 40.13). The request for authorization may not be included on*

the enrollment form (whether in hard copy or in electronic forms available via the plan's website) or made during the processing of a telephonic enrollment.

- *The request for authorization should not be confusing or misleading to members by purporting to have current plan benefit information or by suggesting that the content includes official information from the Medicare program.*

- *These requests for authorization are not subject to review by CMS, and should not be uploaded into HPMS. However, per § 90.21, plan sponsors are still responsible for ensuring that all materials intended for Medicare beneficiaries meet the requirements of this chapter.*

- *CMS is adopting the same requirements for these authorizations as required by the HIPAA Privacy Rule. Additional details on what is required for an acceptable attestation can be found at 45 CFR 164.508.*

170.4 - Sending Non-plan and Non-health Information Once Prior Authorization is Received

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Non-plan and non-health related content cannot be provided to members until after prior authorization is received. Once the authorization is received:

- *Non-health related content cannot be included with plan-related materials. This includes mailings and websites, as well as outbound telephone calls related to current plan information. Note that if the plan sponsor uses a website to provide non-health related content, the link from the plan's Medicare product website must inform the beneficiary that he or she is leaving the Medicare product website and going to the non-Medicare product website as specified in § 100.1.*

- *Health-related content can be included with plan-related materials. (refer to § 40.14.1 – 40.14.6)*

- *As with all other materials that plans send to Medicare beneficiaries, plan sponsors are responsible for ensuring that any non-plan related content provided as a result of beneficiary authorization is accurate and not confusing or misleading, and does not inappropriately imply Medicare's approval, or suggest that the content includes official information from the Medicare program. In addition, these materials should include the disclaimer, "Medicare has neither reviewed, nor endorses, this information." (Refer to § 40.14.6.) This also includes any mailing envelopes in which the non-plan related information is sent. Plan sponsors must also include a plan mailing statement on such materials as specified in § 50.2.*

If the plan sponsor wishes to include the request for authorization in plan mailings, as opposed to a separate mailing at its own expense, the claimed administrative costs must reflect an appropriate reduction to reflect the share of the document preparation and mailings cost that is attributable to the sponsor's efforts to seek authorization to send non-plan related materials. (refer to § 40.14.1 and 40.14.2).

Appendices

Summary of Medicare Advantage

And

Prescription Drug Plan

Technical Instructions

NOTE: These appendices contain only CMS technical instructions/guidance related to items in this chapter. CMS model documents are not included in this chapter therefore; all interested parties should reference the following web links for the specific CMS model documents:

For Part D model documents:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/PartDMMM/list.asp#TopOfPage

For Part C model documents:
http://www.cms.hhs.gov/ManagedCareMarketing/09_MarketngModelsStandardDocumentsandEducationalMaterial.asp#TopOfPage

Appendix 1 - Summary of Benefits

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

[Applies to MA-PD, PDP and MA plans]

CMS expects that the language for sections I and II will be identical to the SB report in HPMS. Any deviation from this language, outside of an approved hard copy change or global hard copy change, will result in CMS disapproval of the material. Deviations include things like the insertion of footnotes, plan specific clarifications, or format alterations except as indicated in the SB instructions. Plans should be generating their SB's via the path in HPMS.

General requirements and guidance for SB are provided below:

1. *Plan sponsors* must adhere to the language and format of the standardized SB and are permitted to make changes only if approved by CMS. Changes in the language and format of the SB template will result in the disapproval of the SB.

2. The title "Summary of Benefits" and the organization's CMS contract number must appear on the cover page of the document.

3. The entire SB must be provided together as one document (e.g., all three sections OR sections one and two if section three is not being utilized).

4. The entire SB must be submitted for review as one document. If plans opt to utilize the premium table and/or Section III *and/or Section IV* ***it*** will result in a forty-five (45) day review.

5. Front and back cover pages are acceptable.

6. Font size of twelve (12) point or larger must be used for the SB. *Plan sponsors* may use bold or capitalized text to aid in readability, provided that these changes do not steer beneficiaries to, or away from, particular benefit items or interfere with the legibility of the document.

NOTE: Since Sections I and II of the SB will not be generated from the PBP in 12 point font, the MA organization should change the font to ensure that the font size is 12 point.

7. Colors and shading techniques are permitted, but must not direct a beneficiary to or away from particular benefit item and must not interfere with the legibility of the document.

8. The SB may be printed in either portrait or landscape page format.

9. *Plan sponsors* offering more than one plan may describe several plans in the same document by displaying the benefits for different plans in separate columns within the benefit comparison matrix (e.g., MA vs. MA-PD) (Section II). However since the

PBP will only print Sections I and II of the SB report for one plan, the *plan sponsor* will have to create a side-by-side comparison matrix for two (or more) plans by manually combining the information into a chart format. *Plan sponsor* using this format must include the following statement in Section I: "Where is <the plan name> available?": "There is more than one plan listed in this Summary of Benefits. If you are enrolled in one plan and wish to switch to another plan, you may do so only during certain times of the year. Please call Customer Service for more information." Since information in Section I will conflict between MA and MA-PD plans, plan sponsors will need to make a hard copy change for Section I in order to reflect accurate information. These side-by-side comparisons are eligible for a 10-day marketing review if no other changes are made to the standardized SB.

10. *Plan sponsors* offering plans with identical benefits within one contract (e.g., one contract S/H/R number), may display the information for these plans in the same column within the benefit comparison matrix (Section II). Plan sponsors using this format must include the following statement in Section I: "Where is <plan name> available?": "If you move out of the state or county where you currently live to a state listed above, you must call Customer Service to update your information. If you don't, you may be disenrolled from <plan name>. If you move to a state not listed above, please call Customer Service to find out if <plan org> has a plan in your new state or county."

11. If the SB describes only one of several plans offered by the organization, the availability of other plans must be noted in the Annual Notice of Change (ANOC).

12. If the SB describes more than one plan, the organization must identify the specific plan in which the member is currently enrolled within the ANOC included with the SB.

13. *Plan sponsors* may include additional information about covered benefits within a separate flyer or other material and may provide this with the SB.

14. The SB header containing such information as the company name, customer service telephone number, only displays on the first page of the SB Section II. It is acceptable for plan sponsors to display the SB header on each page or on each section of the SB. PDPs will not need to print the auto-generated headings which include the S number, PBP number and segment numbers.

15. If an organization chooses to submit an SB for CMS review, without Section III and no hard copy changes, it will be treated as a model without modification and will be reviewed within the ten (10) day time frame.

Additional General Instructions for MA/MA-PD Plans Only
[Applies to MA-PD only and MA only]

1. If an MA organization wants to include mandatory supplemental benefits beyond

those benefits found in the benefit comparison matrix, the MA organization must place the information in Section III of the SB. The MA organization must include a brief description of the benefits and any co-pay requirements.

2. If the MA organization includes additional information about covered benefits in Section III, the MA organization may include a page reference to this information in the appropriate box in the benefit comparison matrix using the following sentence: *"See page < > for information about <benefit category>. Please enter the benefit category exactly as it appears in the left column."*

Instructions for Section I – Beneficiary Information
[Applies to MA-PD, PDP and MA only]

This section, which applies to all plan sponsors, must be incorporated into the SB exactly as it is written within the standardized document, unless otherwise noted.

NOTE: The last sentence in Section I states, *"If you have special needs, this document may be available in other formats."* Plan sponsors contracting with CMS are obligated to follow the regulatory requirements of the Americans with Disabilities Act and the Civil Rights Act of 1964. Compliance with these requirements satisfies the intent of the above referenced SB sentence. No additional requirements are imposed by the above referenced SB sentence.

The following five paragraphs apply to MA and MA-PD plans:

1. Section I, as generated by the PBP, will include the applicable H number and plan number at the top of the document. MA organizations must delete this information.
2. The fourth paragraph (How can I compare my options?) contains a sentence *"We also offer additional benefits, which may change from year to year."* If this is not applicable to your plan, you must remove this sentence.
3. The second question and answer in Section I includes the plan's service area; the PBP will generate a list of counties, with an * indicating those counties that are partial counties. The MA organization may list the zip codes of these counties in this section or provide a cross-reference in Section III and list the zip codes here. The MA organization must also explain in Section I that the * indicates a partial county.
4. The second question and answer in Section I lists the plan's service area, but does not indicate that the information listed represents counties. Therefore, the MA organization must amend the SB so that the answer reads, *"The service area for this plan includes the following counties: <list of counties automatically generated by the PBP>."*
5. Refer to #s 9 and 10 in the SB General Instruction section above for information on additional sentence requirements for Section I of the SB.

Instructions for Section II – Benefit Comparison Matrix

The SB benefit comparison matrix will be generated by the PBP in chart format with the required language. Therefore, the information included in the PBP must first be correct in order for the SB comparison matrix to be correct. The order and content of information presented in the benefit

comparison matrix must be the same as the information presented in the PBP, with the exception of the permitted and/or necessary changes discussed below.

Instructions for Section III – Plan-Specific Features

Section III is used by plan sponsors to describe special features of a program or to provide additional information about benefits described within Sections I and II. Section III is optional and is not standardized with regard to format or content. It may contain text, graphics, pictures, maps.

This section is limited to a maximum of six pages of text and graphics. The page limit is defined as six single-sided pages or three double-sided pages. However, there is one exception to this limit: Plan sponsors translating the SB to another language may add pages as necessary to ensure the translation conveys the same information as the English language version.

Plan sponsors may provide additional information in Section III about covered benefits described within the benefit comparison matrix. If the organization chooses to further describe its covered benefits in Section III, it may reference the information in the relevant section of the benefit comparison matrix using the following sentence: *"See page < > for additional information about (Enter benefit category exactly as it appears in the left column.)"*

All information included in Section III must be verified with the information entered into the PBP report in HPMS.

Section IV of Template for DE Special Needs Plans:

Effective 2010 and beyond, a comprehensive written statement is a MIPPA requirement for all DE SNPs. The purpose of this requirement is to help prospective enrollees to determine whether they can receive any value from enrolling in a SNP. This requirement applies to all DE SNPs regardless of whether they have a contract with the state

Comprehensive written statement must cover benefits and cost sharing information under SNP and State Medicaid plan. A template with the required format is available in HPMS under the bid submission module. In order for plans to describe their benefits, the Section IV SB template can be downloaded using the following navigation path: Plan Bids>Bid Submission>CY XXXX>Documentation>SB Template for DE SNPS.

Adding only Section IV to the SB will trigger a 45-day review process. If a plan does not have a Section III, the Medicaid language does not have to be labeled as Section IV, but it must be distinct from Sections I-III of the SB. Plans should not substitute SB Section III with Section IV. In addition, the format for Section IV is standardized and should be not altered in any way, unless otherwise directed by CMS.

Plan may use the following disclaimers in Section IV of the SB:

1. Applies to all dual SNPs that cover all duals - "The services listed below are available only to those SNP members eligible under Medicaid for medical services."

2. Applies to fully integrated SNPs that have integrated benefits in SB Section II - "Many of the services that are covered by Medicaid are also covered by Medicare through your Medicare Advantage SNP. These services are not listed below. Only the services that may continue when Medicare coverage ends, or which are not covered by Medicare are shown."

Fully Integrated DE SNPs: For fully integrated DE SNPs that meet requirements I- IV, CMS will allow plans to modify Section II of the SB to reflect integrated benefits applicable to each benefit category.

1. Provides dually eligible beneficiaries access to Medicare and Medicaid benefits under a single managed care organization (MCO);
2. Has a contract with a state Medicaid agency that includes coverage of specified primary, acute and, long-term care benefits and services, consistent with State policy, under risk-based financing;
3. Coordinates the delivery of covered Medicare and Medicaid health and long-term care services, using aligned care management and specialty care network methods for high-risk beneficiaries; and
4. Employs policies and procedures approved by CMS and the state to coordinate or integrate member materials, including enrollment, communications, grievance and appeals, and/or quality assurance.

SB Place Holder Sentences: For MA-PD and MA only

Plans have the option to use the prior year's Medicare premium and deductible amounts instead of waiting for CMS to release the new year's amounts. MAOs that apply the Medicare-defined cost sharing for Inpatient Hospital Acute, Inpatient Hospital Psychiatric and Skilled Nursing Facility may also use the prior year's Medicare cost sharing amounts.

Based on this option, for example, the SB will print both the prior year's Medicare cost sharing amounts and a place holder sentence for the new year's Medicare cost sharing amounts. Plan sponsors that need to go to production prior to CMS' release of the Medicare cost sharing may use the prior year's Medicare cost sharing amounts and sentences and delete the new year's placeholder sentences. Plan sponsors that can wait until CMS releases the new year's Medicare cost sharing should use the new year's placeholder sentences and manually update the SB with the new year's Medicare cost sharing when the amounts are released. In addition, these plan sponsors should delete the prior year's Medicare cost sharing amounts and sentences. Medicare Options Compare will automatically display new Medicare cost sharing amounts.

Instructions for Use of Premium Tables in the Summary of Benefits
[Applies to MA-PD, PDP and MA only]

Plans with identical benefits offered in different regions may combine their SB even if their premiums vary between plans by following the requirements below:

- In Section II: Benefit Comparison Matrix, plans must indicate the premium range for all plans listed in the SB. In addition, plans must include a note directing the reader to a *"Premium Table"* that reads *"Please refer to the Premium Table after this section to find out the premium is in your area."*

- The "*Premium Table*" should be located after Section II and before Section III. The table must include only the plan's name, number, service area and premium. Plans may include introductory information about the table and how to use it. However, no other plan information may be included with the *"Premium Table."*

SBs with only Sections I, II and the Premium Table are subject to a 45-day review.

Requests to Change Hard Copy SB
[Applies to all organizations/plan types]

CMS will allow an organization to make changes to hard copy SBs on a very limited basis. All Plan sponsors must obtain hard copy change request approval prior to submitting their SBs to CMS for review.

NOTE:

- Hard copy change requests related to the description of benefits should not be submitted until CMS has approved all bids

- Plans may submit administrative hard copy requests (e.g., changes to local phone or website location) prior to the bid approval

- Hard copy changes are only permitted to correct inaccurate or misleading information or errors generated from the PBP/SB software

- CMS will not allow changes in wording based on individual preferences

- The fact that a hard copy change request was approved in a prior year is no guarantee that it will be approved in a subsequent year

- Any approved hard copy changes will not result in changes to the Medicare Options Compare or to the Plan Benefit Package (PBP)

- Plans should validate the data entered in the PBP as well as reference the SB crosswalk to ensure the correct sentences are generated for the specific benefit being described

- Hard copy changes will not be considered once the PBP is closed for corrections

How to Request a Change
[Applies to MA, MA-PD and PDP]

When requesting a hard copy change, the MA or MA-PD should provide:

- The contract number and PBP #(s) and the regional office reviewer responsible for SB review;
- If the request for change applies to multiple H numbers and plan IDs, the plan may include all applicable H numbers and plan IDs in one e-mail;
- The existing standardized SB language;
- An explanation of why the existing standardized language is inaccurate; and
- A modified sentence.

SB for Section 1876 Cost Plans
[Applies to Section 1876 cost plans – see information below]

Section1876 cost plans are not required to use the standardized Summary of Benefits. If section 1876 cost plan intends to have the plan appear in Medicare Health Plan Compare and Medicare Personal Plan Finder, it will need to complete the Plan Benefit Package (PBP) to create a standardized SB. Section 1876 cost plans that create a standardized SB, they should follow all instructions below. All section 1876 cost plans should follow all instructions previously outlined for the SB. In addition, the following instructions are specific to section 1876 cost plans.

General Instructions

The benefit description column and Original Medicare column must remain unchanged.

All sentences in the plan column of the matrix must be completed with applicable co-pays or co-insurance amounts.

Additional instructions provided in italicized text and in parentheses should be removed from the Summary of Benefits prior to submitting the document to CMS for review.

Unless otherwise indicated, section 1876 cost plans should choose all of the applicable sentences in each category to describe their benefits.

Instructions for Section I- Beneficiary Information Section – For section 1876 cost plans

For section 1876 cost plans that are "closed" to new enrollment, the pre-enrollment language in Section I will not apply ***to existing members***. Therefore, these section 1876 cost plans should include the following disclaimer in their ANOC: *"Existing Cost Plan members should disregard the Introduction of Section I of the Summary of Benefits (SB).*"

NOTE: Any additional information regarding the contractor's "closed status" should also be included in the cover letter.

Instructions for Section II - Benefit Comparison Matrix – For section 1876 cost plans

Section 1876 cost plans may include the following footnote on each page of the benefit comparison matrix. The text of the footnote should appear at the bottom of every page.

"If you go to a provider outside of <insert name of plan>'s network who accepts Medicare patients, you're covered under Original Medicare. You would pay the Part A and Part B deductibles and coinsurance."

Appendix 2 - Attestation Form for Translated Non-English Materials or Alternate Materials

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

Below is the model attestation for translation of Non-English or Alternate Materials that plan sponsors must submit to CMS.

ATTESTATION OF TRANSLATED NON-ENGLISH MATERIALS OR ALTERNATE MATERIALS

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and <insert plan name>, hereafter referred to as the organization, governing the operations of the following plan: <insert plan and contract number>, the plan hereby attests that the non-English or Alternate version(s) submitted in the attached, convey the same information and level of detail as the corresponding English version.

The organization acknowledges that the information concerning the translation(s) described below is for the use of and correspondence to the beneficiary and those misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The organization is submitting to CMS the attestation with the following materials: <INSERT MATERIAL IDENTIFICATION NUMBERS>

Based on my best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in these documents are accurate, complete, and truthful.

_____
(Name & Title <CEO, CFO, or designee able to legally bind the organization>)

On behalf of

_____
(Name of Organization)

_____
Date

Appendix 3 - Plan Sponsor Website Chart

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

The following chart applies only to URL guidelines and plan sponsors website content requirements. Please refer to the applicable sections for specific marketing requirements pertaining to other marketing materials.

Subject		Must Use	Must Not Use	Reason
	URL Guidelines	*All plan sponsors must maintain a Web page, or, if they choose, a website dedicated to the Medicare Advantage or Prescription Drug program.* *All marketing materials can include a Web address that connects to either a corporate website or to the plan's Web page.*		Beneficiaries should be able to find a plan's program information with a minimum of difficulty.
	Website Links	*All links on a plan's website must be clearly labeled with navigational icons that indicate the information contained in the link.* *Any links to health-related or non-health related products/services must be clearly labeled as such.*	*Links to foreign drug sales*	*It should be clear to beneficiary how to navigate the website.*
	Required Information	*All plan sponsors must include a date/stamp on each Web page to inform the beneficiary that the information might not be current.*		
	Contact Information	*The website must contain the plan sponsors toll-free customer service number, TTY number, and either a physical address or Post Office Box address. Plans must also include hours of operation.*		*It is important to make available to beneficiaries different methods to contact the plan.*

Subject		Must Use	Must Not Use	Reason
	Font Size	*All plan sponsors must use a minimum 12-point Times New Roman or equivalent font for all Internet content.*		Neither CMS nor the plan sponsor has any control over the actual screen size shown on individuals' computer screens that can be adjusted by the user. Therefore, the font requirement refers to how the plan sponsor codes the font for the Web page, not how it actually looks on the user's screen.
	Service Area	*For Part D: Regions served by the plan sponsor must be listed. If the Part D plan is a national plan, then it must be identified as such.* *For Part C: The plan must list the state(s), counties and zip codes (only if a partial service is allowed). If the Part C plan is a national plan then it must identify the states.*		
	Benefits	For all plan sponsors: • Applicable conditions and limitations • Premiums • Cost-sharing (e.g., co-payments, co-insurance and deductibles) • Any conditions associated with receipt or use of benefits	*Non-health related products or services may not be presented as benefits*	

Subject		Must Use	Must Not Use	Reason
	Pharmacy List	For Part D plans : • Name addresses phone number and type of pharmacy for all non-chain pharmacies. For chain pharmacies, a local or toll-free number and a TTY number must be provided to find the nearest chain pharmacy location. • Number of pharmacies in network • How the plan meets access requirements (e.g., "<Plan Name> has contracts with pharmacies that equal or exceed CMS requirements for pharmacy access in your area.") *If plan sponsors use a search engine on their websites in lieu of posting the Pharmacy Directory, the search engine must be in compliance with section 100 of the Medicare Marketing Guidelines.*		
	Current Formulary	*All Part D plans and PDPs: Must include a current formulary, updated at least monthly.*		
	Provider Directory	*All MA and section 1876 cost plans must include an electronic provider directory applicable for all products defined by service areas or general geographic area.* *Plans must provide applicable notices with regards to changes that occur in the provider network.*		

Subject		Must Use	Must Not Use	Reason
	Out-of-Network Coverage	*For Part D and PDPs: All Part D plans must include provisions for non-routine access to covered Part D drugs at out-of-network pharmacies, including limits and financial responsibility for access to these drugs.* *For Part C plans: All Part C plans must include provisions with regards to:* • Lock-in • Premiums • Cost-sharing (e.g., co-payments, co-insurance and deductibles) • Rules for obtaining out of network services • Referral rules		
	Coverage Determinations, Organization Determinations, Grievance, Appeals Processes and Procedures	*All Part D* **plans must include a description of** *the* **grievance,** *appeals and* **coverage** *determination* **(including exceptions)** *processes and the procedures members must follow to file a grievance, appeal or request a coverage determination. Additionally, Part D plans must include information on a Web page (located as close to the plan's formulary page as possible) developed specifically for exceptions and appeals.* *All MA plans must include a description of the grievance, appeals and organization determination processes and the procedures members must follow to file a grievance, appeal or request an organization determination.*		

Subject		Must Use	Must Not Use	Reason
	Quality Assurance Policies and Procedures	*All plans must include a description of their quality assurance policies and procedures, including medication therapy management, and drug and/or utilization management, quality assurance activities, and programs provided by Part C plans..*		
	Potential for Contract Termination	*All plans must include a notice of possible contract termination or reduction in service area and the effect these actions may have on its members.*		
	Required Links	*All plans must provide access to the following links:* • Summary of Benefits • Enrollment Instructions and Forms • Evidence of Coverage • LIS Premium Summary Chart • Privacy Notice • Plan Transition Process • Information related to plan's exception and appeals process • Section of CMS ' website regarding Best Available Evidence		*These materials are required for beneficiaries to be able to make an informed choice and to enroll in a particular program.*

Subject		Must Use	Must Not Use	Reason
	If applicable: Notice of Formulary Change	*For all Part D plans and PDPs must provide notice on their website regarding removal or change in the preferred or tiered cost sharing status of a Part D drug.* *The notice must contain the following:* • The name of the affected covered Part D drug; • Information on whether the covered Part D drug is being removed from the formulary, or changing its preferred or tiered cost-sharing status; • The reason why the covered Part D drug is being removed from the formulary, or changing its preferred or cost-sharing status; • Alternative drugs in the same therapeutic category, class or cost-sharing tier, and the expected cost-sharing for those drugs; and • The means by which enrollees may obtain an updated coverage determination or an exception to a coverage determination.		

Appendix 4 - Model File & Use Certification Form

(Rev. 93, Issued: 06-04-10, Effective/Implementation: 06-04-10)

[Applicable to MA, MA-PD, MA only, Section 1876 cost plans]

Pursuant to the contracts(s) between the Centers for Medicare & Medicaid Services (CMS) and (insert organization name), hereafter referred to as the Medicare health plan, governing the operations of the following health plan: (insert health plan name and Contract number), the Medicare health plan hereby certifies that all qualified materials for the above-listed health plan is accurate, truthful and not misleading. Organizations using File & Use Certification agree to retract and revise any materials (without cost to the government) that are determined by CMS to be misleading or inaccurate or that do not follow established Medicare Marketing Guidelines. In addition, organizations may be held accountable for any beneficiary financial loss as a result of mistakes in marketing materials or for misleading information that results in uninformed decision by a beneficiary to elect the plan. Compliance criteria include, without limitation, the requirements in 42 CFR §422.80 and 42 CFR §422.111 for MA plans, and 42 CFR §417.472 and 42 CFR §417.428 for cost-based plans and the Medicare Marketing Guidelines.
I agree that CMS may inspect any and all information including those held at the premises of the Medicare health plan to ensure compliance with these requirements. I further agree to notify CMS immediately if I become aware of any circumstances that indicate noncompliance with the requirements described above.

I possess the requisite authority to make this certification on behalf of the MA organization.

_____
Signature

_____
Name & Title <CEO, CFO, or designee able to legally bind the organization>
On behalf of

_____
Name of Medicare Health Plan

_____
Date

This certification form must be signed and received by the CMS Regional Office prior to submitting materials under the File & Use Certification Process. Once the File & Use Certification form is received, it is effective until further notice from CMS.